PROCEDURE MANUAL OBJECTIVE 2

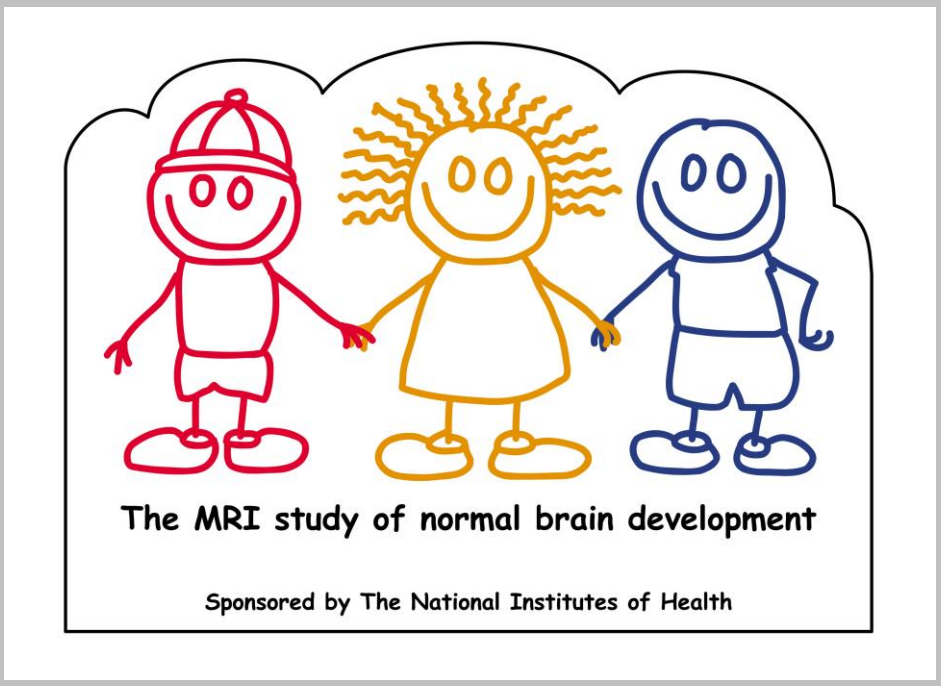


Table of Contents

OVERVIEW

OBJECTIVE – 2

AGES 0:0 - 4:5

(AGES: BIRTH THROUGH 4 YRS., 5 MOS.)

The main goal of the study is to provide a normative database of the developing human brain for comparison with MRI studies of children with neurological, developmental, and psychiatric disorders, and to provide longitudinal data for investigating brain maturation in relation to behavioral and cognitive development in a normal sample.

OBJECTIVE – 2

Alphabet Soup

The MRI Study of Normal Brain Development routinely uses a number of acronyms to describe different parts of the study, they include:

BSID – Bayley Scales of Infant Development-II

CANTAB – Cambridge Neuropsychological Test Automated Battery

CBCL – Child Behavior Checklist

CCC – The CCC is the Clinical Coordinating Center. The CCC is coordinated by Dr. Kelly Botteron and Dr. C. Robert Almli. The CCC is located at Washington University in St. Louis School of Medicine and is responsible for the centralized coordination of the project. This includes the QC Process (both Behavioral QC and Interview QC), tracking recruitment/follow-up progress, developing standardized communication documents like newsletters, recruitment letters, etc.

DAS – Differential Ability Scales

DCC – The DCC is the Data Coordinating Center. The DCC is led by Dr. Alan Evans. The DCC is located at McGill University in Montreal, Quebec, Canada. The DCC supervises the collection of data for the project, especially the collection of MRI data. They are responsible for the design and maintenance of the project database and the public website. They are also responsible for the Database QC.

DPC – Diffusion Tensor Data Processing Center

EDC – Expected Date of Confinement (or due date)

FIGS – Family Interview for Genetic Studies

NIH – The project is funded through the National Institutes of Health. Specifically the project is funded by National Institute of Child Health and Human Development (NICHHD), National Institute of Neurological Disorders and Stroke (NINDS), National Institute of Mental Health (NIMH), National Institute on Drug Abuse (NIDA) and the United States Department of Health and Human Services (DHHS).

PLS-3 – Preschool Language Scales-3

PSC – The PSCs are the Pediatric Study Centers. There are six pediatric study centers through out the country. They are located at Children's Hospital – Boston (this Center has both an Objective 1 and Objective 2 site); Children's Hospital of Philadelphia; Cincinnati Children's Hospital Medical Center; University of California, Los Angeles; University of Texas, Houston Health Sciences Center; Washington University in St. Louis School of Medicine, Objective 1; and Washington University in St. Louis School of Medicine, Objective 2.

PSI – Parenting Stress Index

OBJECTIVE – 2

TRACKING FAMILY & CHILD

CONSENTING

CONSENT & ASSENT FORM

PRIVACY ACT NOTIFICATION STATEMENT

FOUR-FACTOR TABLE

SAMPLING PLAN

AGE CALCULATIONS

TIME WINDOWS FOR SCANNING AND BEHAVIORAL TESTING

OBJECTIVE – 2

CONSENTING

The National Institutes of Health requires that subjects be consented (re-consented) at each timepoint (regardless of scan acquisition). Additionally, consents should include the Privacy Notification Statement provided by NIH and the Privacy Notification Statement should be highlighted as a part of the consenting process.

OBJECTIVE – 2

CONSENT & ASSENT FORM

(Note: Subjects must be reconsented each timepoint. All consent forms should be signed and stored in a separate, confidential file).

Consent Type (verbal or written)	**Adult or Child**	**Date**	**Staff Initials**

PRIVACY ACT NOTIFICATION STATEMENT

THE MRI STUDY OF NORMAL BRAIN DEVELOPMENT
August 9, 2001

PRIVACY ACT NOTIFICATION STATEMENT:

The collection of this information has been authorized under 42 U.S.C. 285(j) and 44 U.S.C. 3101 (Section 301 of the Public Health Services Act). The purpose of this study is to understand brain development in typical healthy children, ranging from newborns to teenagers in order to help us understand the causes of serious childhood conditions like epilepsy, autism and mental retardation.

The primary use of the data collected will be by the researchers involved in the current study to describe typical brain development. This data will also be collected, and through the National Institutes of Health, will become part of a library of typical child and adolescent MRI brain scans and testing data illustrating typical child and adolescent development. You and your child's privacy and confidentiality will be protected at all times. Data is never identified by name but only by anonymous code numbers.

Additional disclosure of the information may be: The MRI scans and other testing data may be used in related research by collaborating researchers and contractors. Your privacy and confidentiality will be protected at all times. There is a possibility that your medical research record may be inspected by officials of the federal government and the University Human Studies Committee.

Participation in this research and furnishing the requested information is voluntary.

OBJECTIVE – 2

SAMPLING PLAN

FOUR – FACTOR TABLE

The MRI Study of Normal Brain Development is responsible for recruiting a sample which is demographically representative of the United States. This is done by dividing the Objective-2 sample based on:

- Age
- Gender (Male of Female)
- Race/Ethnicity: Hispanic/Latino or Not Hispanic or Latino, American Indian or Alaska Native, African American or Black, Asian, Native Hawaiian or Other Pacific Islander, White
- Family Income (High, Medium or Low)

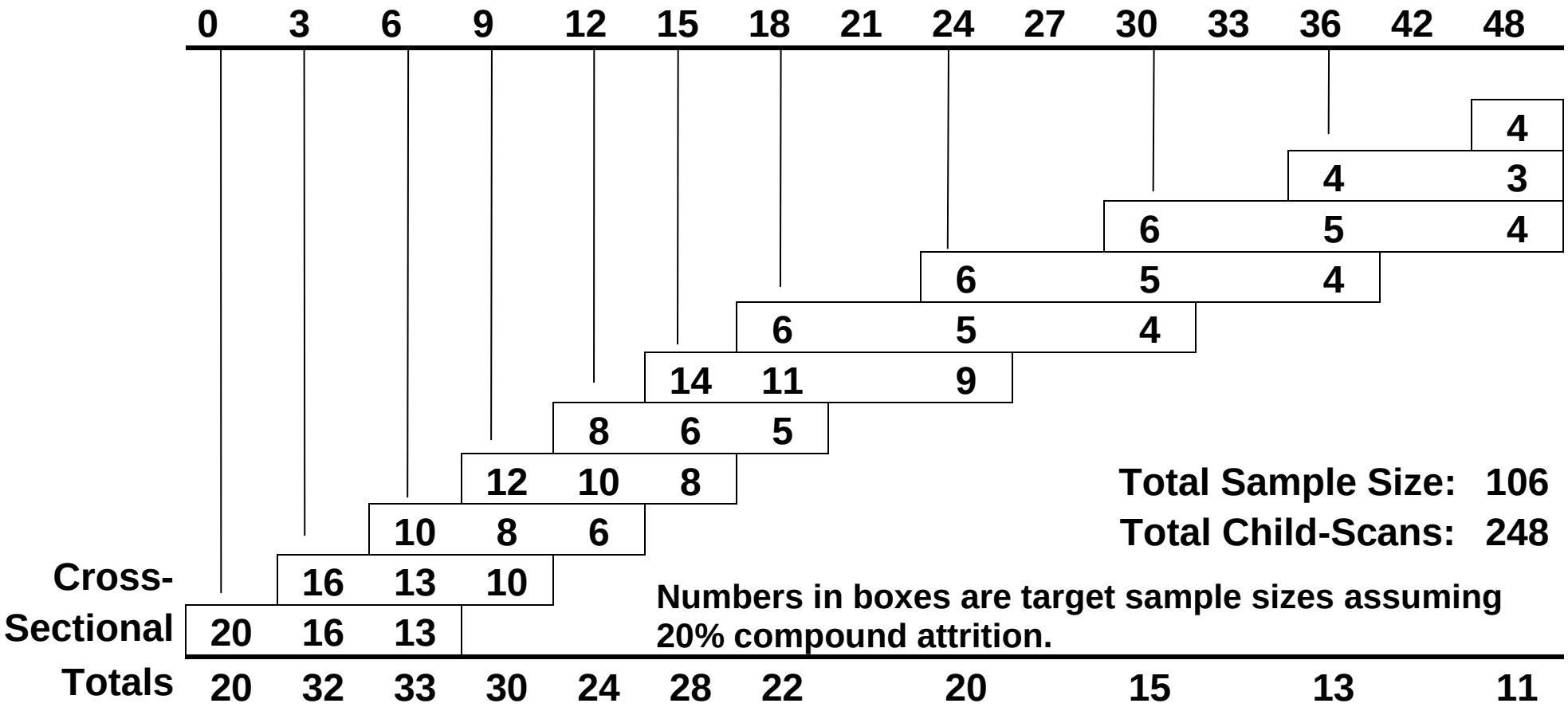
Some individuals are reluctant to indicate a racial group (i.e., they prefer to think of themselves as a member of an ethnic group such as Italian or Scottish as opposed to White). For the purposes of this study, these individuals need to be classified as they would be classified for the U. S. Census. Multi-racial/Multi-ethnic individuals should be classified as their least represented ethnicity (i.e., an African American and Native American child would be listed as Native American for the purposes of the study).

Family income takes into account the gross income of the family, the number of people living in the household and regional cost of living differences. These adjustments are made using data provided by the United States Census Bureau and the United States Department of Housing and Urban Development.

Objective – 2

SAMPLING PLAN

Age (in months)



AGE CALCULATIONS

Because of the rapid development of Objective-2 children, it is important that we use **very** precise age calculations, and that all children have their ages "corrected" to the same point. For Objective-2, all children's ages should be corrected to a Gestational Age of 40 weeks, 0 days. This is done by utilizing the child's Expected Date of Confinement(EDC) or due date for all age calculations, including calculations for neurobehavioral testing.

Additionally, in order to smooth out irregularities between calendar counts (i.e., counting a child's age on the calendar) and hand calculations, an Objective-2 Age Calculator has been developed (see below). The calculator utilizes the Objective-2 Time Windows for Scanning and Behavioral Testing to:

Calculate newborn ages and ensure compliance with the newborn window
Calculate the child's age on a given date
To project a child's age at a date in the future
To calculate compliance with Behavioral Testing and Scanning Windows

Different from the hand calculations the calculator assumes that each year contains 365.25 days (to control for leap year) and each month contains 30.4375 days (to smooth out the difference between 30 and 31 day months).

All ages for Objective-2 should be calculated via the Age and Window Calculator for Objective-2. The calculator is available from the CCC or DCC.

Note: The Age Calculator **does not** check the interval between behavioral testing and scan.

OBJECTIVE – 2

TIME WINDOWS FOR SCANNING & BEHAVIORAL TESTING

1. TARGET AGES & WINDOWS FOR TIMING OF BRAIN SCAN & BEHAVIORAL TESTING

Note that ALL AGES are adjusted to 40-weeks gestational age (Expected Date of Confinement, EDC). Child BRAIN SCAN+BEHAVIORAL TEST (including Neuro Exam) must be conducted within the 'TIME WINDOWS' indicated in Table-1 (e.g., A child in the 0:3 cohort must receive the SCAN+TEST within ±2-weeks of the targeted age of 3-months Post-EDC, while a child in the 4:0 cohort must receive the SCAN+TEST between 4:0 to 4:5 Post-EDC). Special issues regarding the '0:0 cohort' are addressed in Item #3.

Table-1

SCAN-TEST TARGET AGE	TIME WINDOW
*AGE 0:0 (10-14 DAYS POST-EDC)	+ 1-WEEK (See Item #3)
AGE 0:3, 0:6, 0:9, 0:12, & 0:15	± 2-WEEKS
AGE 1:6, 2:0, 2:6, & 3:0	± 4-WEEKS
AGE 4:0	ANY AGE BETWEEN 4:0 TO 4:5 POST-EDC

*THE '0:0 MONTH COHORT' HAS BEEN SET TO '10-14 DAYS POST-EDC' FOR BRAIN SCAN AND BEHAVIORAL TESTING FOR OBJECTIVE-2. (2) THE BIRTH BRAIN SCAN+NEUROLOGICAL EXAM CANNOT TAKE PLACE EARLIER THAN 7 DAYS POST-DELIVERY (as may be necessary when child is born past 40 weeks)..

2. ACCEPTABLE TIME INTERVALS FOR COMPLETION OF BOTH BEHAVIORAL TESTING AND BRAIN SCANNING FOR SPECIFIC TARGET AGES

The intent is to complete the BEHAVIORAL TEST (including Neuro Exam) and BRAIN SCAN for a specific aged child within a few days of one another. However, if circumstances require a longer interval between TEST and SCAN (e.g., a problem with SCAN or TEST), the 'TIME INTERVALS' in Table-2 apply. Note, however, that both TEST and SCAN must be completed within the TIME WINDOWS specified above in Table-1.

Table-2

SCAN-TEST TARGET AGE	TIME INTERVAL
*AGE 0:0 (10-14 DAYS EDC)	1-WEEK
AGE 0:3 THROUGH 2:6	2-WEEKS
AGE 3:0 THROUGH 4:5	4-WEEKS

3. BIRTH (0:0) BRAIN SCAN & NEUROLOGICAL EXAM—A SPECIAL PROBLEM:

Ideally, the 'Birth Scan+Birth Neurological Exam' are to be administered at 10-14 days Post-EDC, but never earlier than 7-days Post-Delivery. As necessary, there is an additional '+1-week window' that can be used for these birth measures, thereby yielding a maximum time period of 10-21 days Post-EDC to complete the Birth Scan+Exam. Calculation of the Target Dates and Window Dates for the

Birth Scan+Exam is a complex process, and some newborns will not fit within the requirements specified above (see Examples and Table-3 below). Thus, a computer program has been developed to calculate the Target Dates and Window Dates for the 0:0 age group (as well as all other age groups under study).

IMPORTANT REMINDER: It is best to schedule the Scan+Exam for the '0:0 cohort' at '10-14 days post-EDC', and only use the '+1-week window' as absolutely necessary, e.g., failed brain scan, cancelled brain scan due to child/mother illness).

EXAMPLES: A child born at "41-wks" must be scanned at exactly 7-days post-delivery to fit within the ideal interval of 10-14 days post-EDC (however, with the +1-week window, the acceptable range is 7-14 days post-delivery). A child born at "41-weeks, 1-day" cannot fit into the ideal interval of 10-14 days post-delivery (however, with the +1-week window, the acceptable range would be 7-13 days post-delivery). A child born at "42-wks" cannot fit within the ideal interval of 10-14 days post-delivery, and would need to be scanned at exactly the 7th day post-delivery to fit within the "+1-week window". Children born at '42 weeks, 1 day' through '42 weeks, 3 days' cannot be Scanned+Examined at "Birth", as they cannot achieve the interval of "at least 1-week post-delivery" and/or the maximum limit of the "+1-week window". Note that these restrictions are peculiar to the "Birth" Scan+Test, and they do NOT apply to children that are scanned at older ages (e.g., 3-months), as long as the Target Ages and the Time Windows are not violated for that age-group (see Table-1).

Table-3

GESTATIONAL AGE AT DELIVERY	**DAYS EARLY (-)** OR LATE (+)	**IDEAL POST-DELIVERY** AGE AT SCAN	**POST-DELIVERY-AGE** +WINDOW AT SCAN
39-wks	-7 days	17 to 21 days	17 to 28 days
40-wks	**0 days**	**10 to 14 days**	**10 to 21 days**
41-wks	+7 days	7 days only	7 to 14 days
41-wks, 1-day	+8 days	cannot achieve	7 to 13 days
42-wks	+14 days	cannot achieve	7 days only
42-wks, 1-day	+15 days	cannot achieve	cannot achieve

OBJECTIVE – 2

EXCLUSION CRITERIA

SCREENING AND EXCLUSION FORM

EXCLUSIONARY MEDICATIONS DURING PREGNANCY & BREASTFEEDING (See Appendix-A-1)

MATERNAL DRUG SCHEDULES (See Appendix-A-2)

OBJECTIVE – 2

SCREENING & EXCLUSION FORM
("RECRUITMENT AND RE-SCREENING VERSION")*

AGES: 0:0 - 4:5

- !!! SCREENING FORM !!! -
EXCLUSION CRITERIA:
"YES" TO ANY BOLD ITEM

Instructions: Circle all terms/words that are applicable when given options in statements (e.g., Circle Mother, Father, or Both, if any of these apply for Item I.A. "Both Mother and Father are Uncomfortable Reading English Documents"). Fill in all data spaces on the form (e.g., Fill in the mother's age in years for Item II.A. "Mother Age _____ years at delivery of recruited child"). Circle "YES" for any Exclusion Statement that applies (Note that all Exclusion statements are in **Bold**). Questioning can be stopped after any Exclusion Statement is answered "YES". The examiner can ask the questions in any order that is deemed appropriate, i.e., you do not have to follow the question sequence on this form.

***NOTE: For RECRUITMENT (INITIAL SCREENING), all items are used (Pages 1-12)**
***NOTE: For RE-SCREENING, only WHITE, NON-SHADED items are used (Pages 4-12**)

I. DEMOGRAPHIC

A. **Both Mother and Father are Uncomfortable Reading English Documents** **YES NO**
(One parent Uncomfortable with Reading English is Not Exclusionary)

B. **Child Adopted or Product of Ovum/Sperm Donation** **YES NO**

C. **Biological Father or Mother with Unknown History (ex. Medical)** **YES NO**

II. PREGNANCY

A. BIOGRAPHICAL - *MATERNAL*

1. **Maternal Age at Recruited-Child's Birth: <16 years or >44 years** **YES NO**
Mother Age _____years at delivery of recruited child

B. INTRA-UTERINE EXPOSURE - *MATERNAL*

1. **Smoking >10 Cigarettes/Week During Pregnancy** **YES NO**

2. **Alcohol Intake >2 Drinks/Week During Pregnancy** **YES NO**

3. **Exclusionary Medications Used During Pregnancy from Appendix A** **YES NO**
List Medications Used, When Used, & How Long Used:

_____

_____

4. **Drugs of Abuse During Pregnancy (ex. Marijuana, Cocaine, Speed)** **YES NO**

C. MEDICAL CONDITIONS DURING PREGNANCY - *MATERNAL*

1. **Placental Abruption** **YES NO**

2. **Preeclampsia with Treatment** **YES NO**
   ex. high blood pressure, water retention, urine protein

3. **Strict Bedrest >6 Weeks Duration** **YES NO**

4. **Pre-delivery Hospital Admissions Related to Pregnancy** **YES NO**

5. **Antepartum Hemorrhage** ("Spotting" Is Not Exclusionary) **YES NO**

6. **Premature Rupture of Membranes > 24 Hours Prior To Delivery** **YES NO**

7. **General Anesthesia During Pregnancy** **YES NO**

8. **Medical Conditions** **YES NO**
   ex. Seizures, Cancer, Blood Transfusion, Phenylketonuria,
   Sickle Cell Anemia Or Trait For Either Mother Or Father, Diabetes
   (Diet-Controlled Diabetes is Not Exclusionary)

9. **Infections Around Time Of Delivery** **YES NO**
   ex. HIV, Sepsis, Toxoplasmosis, Rubella, CMV, Herpes,
   Syphilis (ToRCHeS), Hepatitis, Positive culture (Fever)

III. DELIVERY

A. **C-section Performed Secondary To Fetal Or Maternal Medical Distress** **YES NO**

B. **Multiple Births** **YES NO**

C. **High Forceps Delivery** **YES NO**

D. **Vacuum Extraction** **YES NO**

E. **Breech Or Malpresentation (Not Exclusionary With Planned C-Section)** **YES NO**

IV. BIRTH-NEONATAL - *CHILD*

A. BIRTH DATA

1. Gender: Male Female

2. Birth Date (DOB): _____/_____/_____
   yyyy mm dd

3. Expected Date of Confinement (EDC): _____/_____/_____
   yyyy mm dd

4. Gestational Age at Birth: _____/_____weeks/days

5. Early or Late at Birth (vs. EDC): ____Weeks ____Days (circle: EARLY or LATE)

6. **Born at <37 Weeks 4 Days or >42 Weeks 3 Days** **YES NO**

B. BIRTH GROWTH STATUS

1. **Birth Body Weight <5th % (CDC Form)** **YES NO**
   Birth Weight _____g _____%

2. **Birth Body Length <5th % (CDC Form)** **YES NO**
   Birth Height (Length) _____cm _____%

3. **Birth Head Circumference--OFC <5th % (CDC Form)** **YES NO**
   Birth Head Circum. _____cm _____%

4. **Weight-for-Length or Stature (Height) <5th % (CDC Form)** **YES NO**
   Weight-for-Length or Stature (Height) _____%

NOTE: WEIGHT-FOR-LENGTH EXCLUSION APPLIES ONLY FOR '*BIRTH*' STUDIES (I.E., SCANS AND TESTING AT 10-14 DAYS POST-EDC), NOT FOR '*OLDER*' STUDIES.

5. **Birth Apgar Score <8 at 5-minutes** **YES NO**
   Apgar Score _____1-minute Apgar Score _____5-minute

C. BIRTH CONDITIONS

1. **Seizures (All, Including Febrile Seizures)** **YES NO**

2. **Hyperbilirubinemia Requiring Transfusion, Phototherapy,** **YES NO**
   Or Bili-Blanket >48 Hours, Or, Hospital Re-Admission With Treatment

3. **Structural Abnormalities of Body (Limbs, Head, or Face)** **YES NO**

4. **Medical Conditions** **YES NO**
   ex. Phenylketonuria, Hypothyroidism, Hyperthyroidism, Anemia

5. **Respiratory Distress** **YES NO**
   ex. Chest Compression, Intubation, Ventilator, Supplemental Oxygen, Meconium, Pneumonia

6. **Admitted To Specialized Neonatal Care (ex. NICU)** **YES NO**
   Describe:

_____

_____

7. **Heart Disease or Heart Surgery** **YES NO**

8. **Chromosomal/Congenital Anomalies** **YES NO**
   ex. Down's, Turner's, Klinefelter's, Cleft Lip

9. **Infections** **YES NO**
ex. HIV, CMV, Sepsis, Rubella, Meningitis, Toxoplasmosis, Herpes Syphilis (ToRCHeS), Hepatitis

10. **Abnormal Brain Scan or EEG** **YES NO**

11. **Vision or Hearing Impairment** **YES NO**
ex. Abnormal BAER or Autoacoustic, Retinopathy, Ophthalmia

12. **Tumors or Diaphragmatic Hernia** **YES NO**

V. DEVELOPMENT - *CHILD*

A. CHILD DEMOGRAPHICS

1. **Non-Fluent in English (If Age Appropriate)** **YES NO**

2. **If Breastfeeding: Exclusionary Maternal Medications and Drugs of Abuse** **YES NO**
See Appendix A: List:_____

B. GROWTH MEASURES

1. Child EDC Age At Time Of Growth Measures: _____years _____months _____days

2. Gender: Male Female

3. **Body Weight <5th % (CDC Form)** **YES NO**
Weight _____g _____%

4. **Body Length <5th % (CDC Form)** **YES NO**
Height (Length) _____cm _____%

5. **Head Circumference--OFC <5th% (CDC Form or Nellhaus)** **YES NO**
Head Circum. _____cm _____%

C. PHYSICAL - MEDICAL HISTORY - *CHILD*

1. **Chronic Medical Conditions (ex. Diabetes, Kidney or Liver Problems)** **YES NO**

2. **Metal Implants** **YES NO**
ex. Pacemaker, Electronic Medical Implants, Teeth Braces, Pins

3. **Metal Fragments in Eye or Face** **YES NO**

4. **Non-Removable Body Piercing** **YES NO**

5. **Systemic Rheumatologic Illness or Disorder (ex. Arthritis)** **YES NO**

6. **Malignancy/Cancer** **YES NO**

7. **Significant Heart Disease** **YES NO**

8. **Major Surgery (ex. Neuro, Heart)** **YES NO**

9. **Chemo- or Radiation-Therapy** **YES NO**

10. **Non-Removable Metal Dental Work** **YES NO**
(Braces, Retainer; Tooth Fillings Are Not Exclusionary)

11. **Congenital Abnormalities of Face, Head, or Limbs** **YES NO**

12. **Exclusionary Medications Used During Past Year From Appendix A** **YES NO**
List Medications Used, When Used, & How Long Used:

D. NEUROLOGICAL HISTORY - *CHILD*

1. **Seizures (All, including Febrile Seizures)** **YES NO**

2. **Muscular Dystrophy** **YES NO**

3. **Myotonic Dystrophy (ex. Muscle Disease)** **YES NO**

4. **CNS Infection (ex. Meningitis, Encephalitis)** **YES NO**

5. **Closed Head Injury** **YES NO**
ex. >5 minutes Consciousness Loss, Overnight Hospital Stay

6. **Hearing Impairment Requiring Treatment/Intervention** **YES NO**

7. **Visual Impairment (ex. Strabismus, Visual Disability)** **YES NO**
(Conventional Glasses Correction to 20/40 or Better is Not Exclusionary)

8. **Tuberous Sclerosis (ex. Brain Lesion Causing Seizures, Skin Lesions)** **YES NO**

9. **Neurofibromatosis** **YES NO**

10. **CNS Radiotherapy (ex. Radiation Treatment for Cancer)** **YES NO**

11. **Other Diagnosed/Treated Neurological Conditions** **YES NO**
Describe:

_____

_____

E. INTERVENTION HISTORY - *CHILD*

1. **Significant Language or Learning Disorder Programs Or Treatment** **YES NO**
May Need to Request Records: Early Intervention, Physician, School

2. **Special Types Of Educational Placements** **YES NO**
   May Need to Request Records: Early Intervention, Physician, School

3. **Occupational Therapy** **YES NO**
   Related to Medical/Neurological Exclusion (Current or Past)

4. **Physical Therapy** **YES NO**
   Related to Medical/Neurological Exclusion (Current or Past)

5. **Tested for Lead and Clinic Treatment/Intervention** **YES NO**
   ex. Hospitalization, Medications, Chelation, Change in Diet or Environment

F. PSYCHIATRIC HISTORY- *CHILD*

Requires Clinical (Psychiatric-Specialty) Diagnosis or Treatment (Past or Current)

1. **Mood** **YES NO**
2. **Separation Anxiety** **YES NO**
3. **Conduct Disorder** **YES NO**
4. **Attention Deficit - Hyperactivity Disorder (AD-HD)** **YES NO**
5. **Obsessive-Compulsive Disorder (OCD)** **YES NO**
6. **Pervasive Developmental Disorder ([PDD] ex. Autism, Asperger's)** **YES NO**
7. **Tic Disorder (ex. Motor and Vocal)** **YES NO**
8. **Childhood Disintegration Disorder** **YES NO**
9. **Rett's Disorder** **YES NO**
10. **Reactive Attachment Disorder** **YES NO**
11. **Feeding Disorder of Infancy** **YES NO**
12. **Pica** **YES NO**
13. **Rumination Disorder** **YES NO**
14. **Selective Mutism** **YES NO**
15. **Tourette's Syndrome** **YES NO**
16. **Stereotypic Movement Disorder** **YES NO**

VI. PSYCHIATRIC HISTORY--*FAMILY (1st DEGREE RELATIVES)*

Biological Parents and Full Biological Siblings ONLY!

*Screen column (circle 'YES' if the exclusion occurs during the 'Screening Interview')
*FIGS column (circle 'YES' if the exclusion occurs during the 'FIGS Interview')

Disorder	Relationship to Recruited Child	*Screen	*FIGS
A. **Schizophrenia**	_____	**YES NO**	**YES NO**
B. **Bipolar/Manic Depressive Disorder**	_____	**YES NO**	**YES NO**
C. **Chronic/Recurrent Major Depression**	_____	**YES NO**	**YES NO**
D. **Psychotic Disorder**	_____	**YES NO**	**YES NO**
E. **Pervasive Developmental Disorder (PDD)**	_____	**YES NO**	**YES NO**
F. **Obsessive-Compulsive Disorder (OCD)**	_____	**YES NO**	**YES NO**
G. **Attentional Deficit - Hyperactivity Disorder (ADHD)**	_____	**YES NO**	**YES NO**
H. **Alcohol Dependence**	_____	**YES NO**	**YES NO**
I. **Substance Dependence (Not nicotine)**	_____	**YES NO**	**YES NO**
J. **Tourette Disorder**	_____	**YES NO**	**YES NO**
K. **Antisocial Personality Disorder**	_____	**YES NO**	**YES NO**
L. **Inherited Neurological Disorder**	_____	**YES NO**	**YES NO**
M. **Mental Retardation: Non-Traumatic (ex. Genetic)**	_____	**YES NO**	**YES NO**

VII. CHILD-TESTING AND PARENTAL-FORM MEASURES

A. **BSID-II: Mental Developmental Index--MDI Score <70** (100±15) **YES NO**

Child's MDI Score: _____

B. **BSID-II: Psychomotor Developmental Index--PDI Score <70** (100±15) **YES NO**

Child's PDI Score: _____

C. **PLS-3: Total Language Standard (TLS) Score <70** (100±15) **YES NO**

Child's TLS Score: _____

D. **DAS General Conceptual Ability Score--GCA Score <70** (100±15) **YES NO**

Child's GCA Score: _____

E. **CBCL Score >70 On 'Total Problem Scale' Or Any 'Problem Scale'** (50±10) **YES NO**

Total Problem T-Score: _____ Total Problem Percentile:_____

If T-score on any 'Problem Scale' is > 70, Fill In Below:

Name of Scale:	T-Score:	Percentile:
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

VIII. NEUROLOGICAL EXAM - *CHILD*

Neurological Exam: 0:0 -- 0:1

1. **Presence of the following Facial Dysmorphisms:**	**YES**	**NO**
a. repaired or unrepaired palatal cleft ___		
b. repaired or unrepaired labial cleft ___		
c. facial stigmata of Sturge Weber disease ___		
d. facial stigmata of tuberous sclerosis ___		
2. **Mild, moderate, or severe hypertonia**	**YES**	**NO**
3. **Mild, moderate, or severe hypotonia**	**YES**	**NO**
4. **Strength <4/5**	**YES**	**NO**
5. **>10 beats of clonus at ankles**	**YES**	**NO**
6. **Clonus at site other than ankle**	**YES**	**NO**
7. **Dystonia**	**YES**	**NO**
8. **Choreoathetosis**	**YES**	**NO**
9. **Tremor**	**YES**	**NO**
10. **Tics**	**YES**	**NO**
11. **Any clearly noticeable exo- or esotropia**	**YES**	**NO**
12. **Jerk, pendular, rotatory, or monocular nystagmus**	**YES**	**NO**
13. **Asymmetry of facial movement**	**YES**	**NO**
14. **Abnormal Visual Fields**	**YES**	**NO**
15. **Ocular Motility Disturbance**	**YES**	**NO**
16. **Strabismus**	**YES**	**NO**
17. **Markedly Abnormal Facial Movement**	**YES**	**NO**

Neurological Exam: 0:2 – 0:11

1. **Presence of the following facial dysmorphisms:**	**YES**	**NO**
a. repaired or unrepaired palatal cleft ___		
b. repaired or unrepaired labial cleft ___		
c. facial stigmata of Sturge Weber disease ___		
d. facial stigmata of tuberous sclerosis ___		
2. **Mild, moderate, or severe hypertonia**	**YES**	**NO**
3. **Mild, moderate, or severe hypotonia**	**YES**	**NO**
4. **Strength <4/5**	**YES**	**NO**

5. **>5 beats of clonus at ankles (for children 2-4 months of age); any ankle clonus in children > 4 months of age** **YES NO**
6. **Clonus at site other than ankle** **YES NO**
7. **Dystonia** **YES NO**
8. **Choreoathetosis** **YES NO**
9. **Tremor** **YES NO**
10. **Tics** **YES NO**
11. **Dysmetria** **YES NO**
12. **Ataxia** **YES NO**
13. **Any clearly noticeable exo- or esotropia** **YES NO**
14. **Jerk, pendular, rotatory, or monocular nystagmus** **YES NO**
15. **Asymmetry of facial movement** **YES NO**
16. **Abnormal Visual Fields** **YES NO**
17. **Ocular Motility Disturbance** **YES NO**
18. **Strabismus** **YES NO**
19. **Markedly Abnormal Facial Movement** **YES NO**
20. **Cannot sit independently by 8 months** **YES NO**
21. **Cannot roll from front to back or back to front by 6 months** **YES NO**
22. **Tonic neck reflex not absent by 7 months** **YES NO**

Neurological Exam: 1:0 – 2:11

1. **Presence of the following facial dysmorphisms:** **YES NO**
   - **a. repaired or unrepaired palatal cleft** ___
   - **b. repaired or unrepaired labial cleft** ___
   - **c. facial stigmata of Sturge Weber disease** ___
   - **d. facial stigmata of tuberous sclerosis** ___
2. **Mild, moderate, or severe hypertonia** **YES NO**
3. **Mild, moderate, or severe hypotonia** **YES NO**
4. **Strength <4/5** **YES NO**
5. **Clonus at any site** **YES NO**
6. **Dystonia** **YES NO**
7. **Choreoathetosis** **YES NO**
8. **Tremor** **YES NO**
9. **Tics** **YES NO**
10. **Dysmetria** **YES NO**

11. **Ataxia** **YES NO**
12. **Any clearly noticeable exo- or esotropia** **YES NO**
13. **Jerk, pendular, rotatory, or monocular nystagmus** **YES NO**
14. **Asymmetry of facial movement** **YES NO**
15. **Abnormal Visual Fields** **YES NO**
16. **Ocular Motility Disturbance** **YES NO**
17. **Strabismus** **YES NO**
18. **Markedly Abnormal Facial Movement** **YES NO**
19. **No babbling by 12 months** **YES NO**
20. **No expressive language (word expression) by 24 months** **YES NO**

Neurological Exam: 3:0 – 4:5

1. **Presence of the following facial dysmorphisms:** **YES NO**
   - **a. repaired or unrepaired palatal cleft** ___
   - **b. repaired or unrepaired labial cleft** ___
   - **c. facial stigmata of Sturge Weber disease** ___
   - **d. facial stigmata of tuberous sclerosis** ___
2. **Mild, moderate, or severe hypertonia** **YES NO**
3. **Mild, moderate, or severe hypotonia** **YES NO**
4. **Strength <4/5** **YES NO**
5. **Clonus at any site** **YES NO**
6. **Dystonia** **YES NO**
7. **Choreoathetosis** **YES NO**
8. **Tremor** **YES NO**
9. **Tics** **YES NO**
10. **Dysmetria** **YES NO**
11. **Ataxia** **YES NO**
12. **Any clearly noticeable exo- or esotropia** **YES NO**
13 **Jerk, pendular, rotatory, or monocular nystagmus** **YES NO**
14. **Asymmetry of facial movement** **YES NO**
15. **Abnormal Visual Fields** **YES NO**
16. **Ocular Motility Disturbance** **YES NO**
17. **Strabismus** **YES NO**
18. **Markedly Abnormal Facial Movement** **YES NO**

OBJECTIVE – 2

STEPS FOR CHILD CONTACT & RECRUITMENT

THESE STEPS CAN BE ACCOMPLISHED VIA FACE-TO-FACE, U.S. MAIL, MEDICAL RECORD REVIEW, AND/OR TELEPHONE CONTACT, AS APPROPRIATE

STEPS FOR CHILD RECRUITMENT AND RETENTION

CONTACT SHEET

CONTACT RECORD

TRACKING SUBJECTS WITH THE TRACKING LOG (See Appendix-B)

OBJECTIVE – 2

STEPS FOR CHILD RECRUITMENT AND RETENTION

1. All Items Below Can Be Achieved Via Face-to-Face Contact, Medical Records review, or Mail Contact (as appropriate)
   - Contact parents at hospital, well-baby clinics, etc.
   - Introductory Letter to parents
   - Brochure
   - Incentive (Refrigerator Magnet)
   - Reply Postcard and Business Reply Envelope
   - Child 'Brain Mapping' Article (optional)
   - Public website (http://www.brain-child.org/)

2. Administer Screening and Exclusion Form.

3. Put child's information in Objective-2 Tracking Log.

4. If Screening and Exclusion "OK", Provide:
   - CBCL Cover Letter
   - Study Description
   - Consent Form
   - CBCL (Child Behavior Check List) if Age-Appropriate
   - Payment form
   - 9 x 12 Business Reply Return Envelope for Returning CBCL
   - Privacy Act Notification Statement

5. If CBCL, Consent Form, and payment form received:
   - Score CBCL
   - Mail incentive ($10 gift certificate)
     - If CBCL fail (Any subscale >70), include *Ineligible* cover letter with incentive
     - If CBCL pass (All subscales ≤70), include *Next Step Letter* with incentive, and schedule any additional screening procedures

6. IF CBCL, etc. NOT received:
   - Call to inquire about receipt of CBCL, Consent Form, and Payment Form
   - Resend CBCL, Consent Form, Payment Form, and return envelope as needed
   - When received, score CBCL
   - Mail incentive ($10 gift certificate)
     - If CBCL fail (>70), include *Ineligible* cover letter with incentive
       If CBCL pass (≤70), include with incentive, *Next Step* cover letter, and Payment form
   - If CBCL Passed, Meet or Call to administer FIGS
     If FIGS OK, mail incentive ($20 gift certificate) with *Next Step* cover letter
     If FIGS not OK, mail $20 incentive and *Ineligible* cover letter of explanation

7. If pass all Screeners, make Follow Up Call to parent to invite family to participate. Set up first Behavioral Testing-MRI appointment with parent. Use Phone Message Frequency Guidelines.

8. Use database to set up PSC/DCC ID for child.

9. Send MRI Consents (if not already done so) and confirmation letter at least 1 week prior to first MRI appointment.

10. Call the parent the day before appointment to confirm that the child is in good health and ready to come to the center the following day. Inquire about possible viral exposure. Also confirm receipt of consent forms, and remind parents to bring forms to the appointment.

11. First Behavioral Testing-MRI appointment (In House Testing).

12. Send Thank You letter

13. Send Birthday cards

14. Send bi-annual study newsletter. All sites use same newsletter, provided by DCC.

15. Re-screen family prior to second and any additional Behavioral Testing-MRI Administrations.

16. Telephone Contact to schedule next Behavioral Testing-MRI appointment.

OBJECTIVE – 2

CONTACT SHEET

1. BIOLOGICAL MOTHER

Name:_____

Address: Street & Apt. #:_____

_____

City-State-Zip Code:_____

Telephone: Home:_____Work:_____

Telephone: Cell:_____Pager:_____

E-Mail:_____

FAX:_____

Social Security Number (for Reimbursement):_____-_____-_____

2. BIOLOGICAL FATHER

Name:_____

Address: Street & Apt. #:_____

_____

City-State-Zip Code:_____

Telephone: Home:_____Work:_____

Telephone: Cell:_____Pager:_____

E-Mail: _____

FAX: _____

Social Security Number (for Reimbursement):_____-_____-_____

3. THE CHILD

Child's Name:_____

Social Security Number (for Reimbursement):_____-_____-_____

OBJECTIVE – 2

CONTACT RECORD

Do not record PHI on this form. If PHI is accidently recorded, it should be crossed out when the chart is copied.

Date	Time (A or P)	Rater	Comments

OBJECTIVE – 2

TOOLS FOR CHILD CONTACT

INTRODUCTORY LETTER TO PARENTS (ZIP CODE RECRUITMENT)

INTRODUCTORY LETTER TO PARENTS (COMMUNITY RECRUITMENT)

BROCHURE

REPLY POSTCARD

PHONE MESSAGE FREQUENCY GUIDELINES

CBCL COVER LETTER TO PARENTS

DESCRIPTION OF STUDY

PAYMENT FORM EXAMPLE

INELIGIBLE LETTER – AFTER INITIAL SCREENING

INELIGIBLE LETTER – AFTER FULL SCREENING PROCESS

NEXT STEP LETTER FOLLOWING CBCL

NEXT STEP LETTER AFTER FULL SCREENING

CBCL SCORED, “OK” FOR STUDY

FOLLOW-UP CALL: CBCL NOT YET RECEIVED

CALL TO SCHEDULE IN-HOUSE TESTING AND MRI

CONFIRMATION LETTER FOR TESTING AND MRI SCAN DAY

TELEPHONE CALL TO CONFIRM NEXT DAY CENTER APPOINTMENT

THANK YOU LETTER

MISSING PARENT FORMS LETTER

UNRETURNED PHONE MESSAGES LETTER

FINAL LETTER: STUDY COMPLETION

BIRTHDAY CARD

SAMPLE NEWSLETTER

OBJECTIVE – 2

INTRODUCTORY LETTER TO PARENTS (ZIP CODE RECRUITMENT)

Title First Name Last Name
Address
City, State Zip

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Dear Title. X:

We are writing to invite you to participate in an important research study sponsored by the National Institutes of Health, being conducted at [site]. The National Institutes of Health (NIH) is the government agency that sponsors most of the medical research in the United States, including ongoing studies of healthy brain development as well as childhood brain disorders.

This new study is known as **The MRI Study of Normal Brain Development**, and is authorized by federal law (specifically, Title 42, Section 285-j and Title 44, Section 3101 of the United States Code and Section 301 of the Public Health Services Act). The purpose of this study is to understand brain development in typical healthy children, ranging from newborns to teenagers, so that their brains can be compared to those of children who have childhood brain disorders. This information can help us understand the causes of serious childhood conditions like epilepsy, autism, and mental retardation.

Scientists in six cities around the country are participating. [Site] is inviting families in the [city] area to join the study. Your family was randomly selected based on zip code location and the possible presence of children in the household. A national market research firm provided this information to us.

This study uses the technique of magnetic resonance imaging (MRI). This is a safe and painless method of taking pictures of the brain. There will be no radiation, medication or needles used in our study. In addition to the MRI scanning, your child will be asked to complete some tests of their abilities and psychological development. Your child will also receive a neurological examination by a physician. There are no blood samples. Finally, you will be interviewed about your family history and your child's development. The enclosed brochure further describes the study. We recognize that participating in this study will involve some of your time and energy. You will receive compensation for your time. The benefit to medical science will be much needed information about normal brain development.

This study is completely voluntary. Be assured that there are no penalties if you decide not to respond, either to this letter, or at any stage of the study. If you decide to participate, you will be reimbursed for your time, and receive a written report of your child's psychological testing results. The information you provide will be kept confidential. One likely use of the information is in research on childhood illnesses, where collaborating researchers and contractors may be allowed access to the resulting data. Your privacy and confidentiality will be protected at all times.

In a week or so, a member of our staff will be calling to ask if you are willing to learn more about the study. You will be asked some questions to determine whether or not your child might be eligible to participate. If you do not wish to be contacted, just return the enclosed post card. If you would like to learn more about the study, you may wish to return the post card and let us know convenient times to call you. We've enclosed an article about this study of children's brain development and MRI from the April 2001, edition of Child magazine.

We hope you will consider participating in this important study. If you have any questions or concerns, please call our Project Coordinator, [name] at [phone number].

Sincerely, [Principal Investigator and title]

OBJECTIVE – 2

INTRODUCTORY LETTER TO PARENTS (COMMUNITY RECRUITMENT)

Title First Name Last Name
Address
City, State Zip

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Dear Title. X:

We are writing to invite you to participate in an important research study sponsored by the National Institutes of Health, being conducted at [SITE]. The National Institutes of Health (NIH) is the government agency that sponsors most of the medical research in the Unites States, including ongoing studies of healthy brain development as well as childhood brain disorders.

This new study is known as The MRI Study of Normal Brain Development, and is authorized by federal law (specifically, Title 42, Section 285-j and Title 44, Section 3101 of the United State Code and Section 301 of the Public Health Services Act). The purpose of this study is to understand brain development in typical, healthy children, ranging from newborns to teenagers, so that their brains can be compared to those of children who have childhood brain disorders. This information can help us understand the causes of serious childhood conditions like epilepsy, autism, and mental retardation.

Scientists in six cities around the country are participating. [SITE] is inviting families in the [CITY] area to join the study.

This study uses the technique of magnetic resonance imaging (MRI). This is a safe and painless method of taking pictures of the brain. There will be no radiation, medication or needles used in our study. In addition to the MRI scanning, your child will be asked to complete some tests of their abilities and psychological development. Your child will also receive a neurological examination by a physician. There are no blood samples. Finally, you will be interviewed about your family history and your child's development. The enclosed brochure further describes the study. We recognize that participating in this study will involve some of your time and energy. You will receive compensation for your time. The benefit to medical science will be much needed information about normal brain development.

This study is completely voluntary. Be assured that there are no penalties if you decide not to respond, either to this letter, or at any stage of the study. If you decide to participate, you will be reimbursed for your time, and you will receive a written report of your child's psychological testing results. The information you provide will be kept confidential. One likely use of the information is in research on childhood illnesses, where collaborating researchers and contractors may be allowed access to the resulting data. Your privacy and confidentiality will be protected at all times.

If you would like to learn more about the study, please call [NAME OF RECRUITER] at [XXX-XXX-XXXX]. I have enclosed a Description of Study, a Privacy Act Notification Statement, a brochure, and the screening consent form along with a return self addressed stamped envelope.

We hope you will consider participating in this important study.

Sincerely, [Principal Investigator and title]

BROCHURE (page 1)

What does it feel like inside the scanner?

Children will be positioned comfortably on a scanning bed that slides into the tunnel-shaped magnet. When the scanner is turned on, it makes humming and knocking sounds. Earmuffs or earplugs will be provided. An intercom system allows the child and technologist to speak to each other at all times.

Parents may accompany their child into the scanning area.

Participating Centers

Children's Hospital, Boston

The Children's Hospital of Philadelphia

Cincinnati Children's Hospital Medical Center

University of California, Irvine

University of California, Los Angeles

University of Texas Health Science Center at Houston

Washington University, St. Louis

Clinical Coordinating Center
Washington University, St. Louis

Data Coordinating Center
Montreal Neurological Institute ,
In collaboration with
Argosy Inc./Georgetown University
Harvard University/ McLean Hospital
University of California, Los Angeles

For more information, please visit our web site www.brain-child.org, **or contact us at:**

Version: May 2, 2002

The MRI Study of Normal Brain Development

Sponsored by

The National Institute of Mental Health

NIMH National Institute of Mental Health

The National Institute of Child Health and Human Development

The National Institute of Neurological Disorders and Stroke

BROCHURE (page 2)

Why is this research study being done?

The goal of this study is to learn more about how the brain develops in typical, healthy children and adolescents. By using Magnetic Resonance Imaging (MRI), a safe and painless procedure, changes in the brain can be observed and related to thinking, feeling, and behavior.

This study will enroll approximately 500 children, ranging from infancy to young adulthood, who will be seen at different time points over a six-year period. It will involve seven different sites across the United States as well as a central Data Coordinating Center in Montreal, Canada, and a Clinical Coordinating Center in St. Louis, Missouri.

The information obtained during the study will provide essential knowledge for scientists for years to come. It can help us understand the causes of serious childhood conditions like psychosis, obsessive-compulsive disorder, epilepsy, autism, and mental retardation.

What is MRI?

MRI, or magnetic resonance imaging, is a safe and painless way to take pictures of the brain by using a large magnet, radio waves and a computer. The tunnel-like magnet around the individual sets up a strong magnetic field. Radio waves, like those detected by a radio, are transmitted and interact with water molecules in the body that are in "resonance." These water molecules send out signals that the computer turns into images. Very detailed pictures of the brain are created from the images. MRI does not use x-rays and the magnetic fields have no known harmful effects.

MR image from the scan of a 13-year-old.

Who should participate?

Normal, healthy infants, children and adolescents may participate in this study. Children generally enjoy the attention and testing and may be offered a picture of their brain obtained from the MRI scan to take home with them.

Before the MRI, children and parents will be asked to fill out a form asking if there are any metal or battery-operated devices in their body. Some metal objects are not allowed for safety reasons. Some examples are metal plates, clips, staples, and implanted devices like pacemakers. While it is safe to be scanned with other metal objects such as dental fillings and braces, they may cause distortion in the images.

What will happen during the study?

During the study, children will complete tests that measure memory, attention, language and motor skills. They may be asked to answer questions, solve problems, and do tasks that are similar to video computer games. They will have a neurological examination and parents will be interviewed about their child's development, behavior and feelings. Children will undergo MRI scans.

Infants and toddlers will have their behavior and development assessed by experts using playful, colorful objects. Little ones may be scanned during sleep and will be closely attended.

Families will be compensated for their time. All of the information obtained in this study will be kept private and confidential.

OBJECTIVE – 2

REPLY POSTCARD

3 1/2 X 6 1/4 card stock reply card with 3 5/8 X 6 1/2 inch business reply envelope

The MRI study of normal brain development
Sponsored by the National Institutes of Health

O YES I would like to find out more about the MRI Study.

Please call me at ( ) __ __ __ -- __ __ __ __

The best times to reach me are: _____

O NO I am not interested in participating.
Please do not contact me further.

OBJECTIVE – 2

PHONE MESSAGE FREQUENCY GUIDELINES

Script for message left on answering machine: "Hello, this is [name] calling from [institution] for [parent name], about the National Institutes of Health study that we'd like to invite you to join. I'll call back another time, or you can call me at [phone number]. Thank you."

Script for message left with person who answers phone: "This is [name] calling from [institution]. I'll call back another time. Thank you."

If responsible adult answers, consider leaving a longer message for parent, including your name, purpose of call, name of study, and phone number.

Script for child who answers phone: "This is [name]. I'll call again. Thank you."

Guidelines for number of messages left:

1. Leave voicemail (VM) message on answering machine (using script above) 1 time a week, up to 3 times in a 4-week period.

2. Call without leaving a message no more than 3 times a week, in addition to one VM per week.

3. Do not leave messages with children.

4. Vary time of day and day of week for calls.

5. After 3 weeks of no contact, CONSIDER FAMILY UNAVAILABLE.

OBJECTIVE – 2

CBCL COVER LETTER TO PARENTS

Title First Name Last Name
Address
City, State Zip

Dear Title. X:

Thank you for your willingness to consider participating in The MRI Study of Normal Brain Development Project. We are enclosing a number of items in this package:

- A description of the study
- Two copies of the Consent form approved by the Clinical Investigation Committee at _____ _____. This form gives permission for a member of our staff to call your home and ask you the questions in the screening interview. This form also gives permission for us to conduct one more interview with you by phone if the screening interview indicates that your child is eligible. Please read the form carefully, sign one, and return it with the enclosed questionnaire. Please keep the other copy for your records.
- Privacy Act Notification Statement
- A questionnaire called the Child Behavior Checklist
- A payment form for you to complete and return, so that we may compensate you for participating (Please fill out highlighted areas only).

At this point we would like to find out some additional information about your child. If you agree to continue in the study, please return the signed Consent form, the completed Child Behavior Checklist questionnaire about your child, and the completed payment form [may not apply to all sites] so that we may compensate you for your participation. Please use the enclosed postage-paid return envelope. Upon receipt of these items, we will contact you about further participation in the study.

To compensate you for your time and support, we will send you a $10.00 gift certificate to _____ upon the return of (1) the signed Consent form, (2) payment form, and (3) the completed Child Behavior Checklist questionnaire.

Thank you for your interest in this study. If you have any questions or comments, please call our project coordinator, [name] at (__) .

Sincerely,
XXX

OBJECTIVE – 2

DESCRIPTION OF STUDY (ZIP CODE RECRUITMENT)

You and your child are invited to participate in a research study conducted by Dr. _____ and his/her colleagues at_____.

The purpose of this research is to learn more about how the brain develops and how this relates to thinking, feeling, and behavior in children and adolescents. In order to learn about brain development, families with children and adolescents in 6 cities in the United States are being contacted and asked to participate in the study. As a participant in the study your child will receive:

A full neurological exam
Cognitive/Behavioral testing with results provided to parents
An MRI of the brain
Monetary reimbursement for your time and effort

For the first phase of the study you will be asked about many different aspects of your child's and your family's life. The initial questions will help find out whether your child meets all the special conditions that the children participating in this study are asked to meet.

The second group of questions will then help us to describe in more depth the children who are taking part in the study. Once your child is part of the study he/she will have a Magnetic Resonance Imaging scan (MRI), a brief physical and a neurological examination by a [name of site] physician, an evaluation of skills and abilities, and interviews. The MRI scan takes pictures of your child's brain and is considered safe. MRI scans are done everyday on many children, in many hospitals, all around the country. The medical examination is like the examination that your family doctor would perform. The skills and abilities measures are like what the child would do at school. This visit will take up to 6 hours to complete and will be scheduled at your convenience.

Should you choose to participate in the study, you will be invited back for follow-up sessions at approximately three to six month intervals for infants, toddlers, and preschool children. The purpose of this is to track the development of your child's learning and behavior and the development of the brain. We will also ask you to complete some questionnaires about your child.

We will pay all expenses for travel, parking and lunch. We will also compensate you for your time and effort in participating in the study.

OBJECTIVE – 2

PAYMENT FORM EXAMPLE

Document No. _____ *(for systems processing)*
Date Processed ____/____/____

[Name of Institution]

Consent for Participation in Research Activities and Request for Payment

This will serve to certify that _____ is to be paid
(Participant's Name)

$ _____ **in the form of a gift certificate for their voluntary participation in a research study on** _____/_____/_____ ***(Date)***

Any questions that I have about this procedure have been answered satisfactorily and I have been informed of my freedom to defer from answering any questions.

_____
Participant Signature *(must be in ink)*

Please do not write in area below:

Investigator's Signature
Investigator's Name The MRI Study of Normal Brain Development
Grant or Study Name
University Fund Number

Participant's Social Security Number

Current Address (Please Print)

City (Please Print) State

Zip Code

Participant Number (for office use only)

* Participant number in lieu of other personal data for confidentiality studies. Principal Investigator must retain this data on file.

Please return this completed form to receive your gift certificate. You should receive your gift certificate in 2 to 3 weeks.

OBJECTIVE – 2

INELIGIBLE LETTER-- AFTER INITIAL SCREENING

To be sent:

1. If any CBCL subscale >70 OR
2. If Exclusionary criteria makes child ineligible

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Date

Respondent Name
Address
City, State, Zip

Dear [Respondent Name]:

Thank you for participating in the MRI Study of Normal Brain Development. Your time and effort in answering our questions are an important contribution to the National Institutes of Health research into children's health. We are enclosing a $10 gift certificate in appreciation.

As with all large research studies of this type, some families are selected to continue to the next phase, and some are not. Sometimes this selection is made at random, and sometimes it is made on the basis of meeting a very specific requirement in the area of interest to the researchers in the study. At this time, we do not anticipate contacting you further for this study.

We wish you and your family good health. Thank you again for your participation.

Sincerely,

Name of investigator

OBJECTIVE – 2

INELIGIBLE LETTER--AFTER FULL SCREENING PROCESS

To be sent:

1. If any CBCL subscale >70 OR
2. If Exclusionary criteria makes child ineligible
3. If does not pass all screeners

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Date

Respondent Name
Address
City, State, Zip

Dear [Respondent Name]:

Thank you for participating in the MRI Study of Normal Brain Development. Your time and effort in answering our questions are an important contribution to the National Institutes of Health research into children's health. We are enclosing a $20 gift certificate in appreciation.

As with all large research studies of this type, some families are selected to continue to the next phase, and some are not. Sometimes this selection is made at random, and sometimes it is made on the basis of meeting a very specific requirement in the area of interest to the researchers in the study. At this time, we do not anticipate contacting you further for this study.

We wish you and your family good health. Thank you again for your participation.

Sincerely,

Name of investigator or coordinator

OBJECTIVE – 2

NEXT STEP LETTER FOLLOWING CBCL

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Date

Respondent Name
Address
City, State, Zip

Dear [Respondent Name]:

Thank you for your participation in the MRI Study of Normal Brain Development. Your time and effort in answering our questions are an important contribution to the National Institutes of Health research into children's health. We are enclosing a $10 gift certificate in appreciation.

At this time, we would like to invite you to participate in the next step in the study. In the next few weeks, one of our interviewers will call to give you the details, or you may call us directly at [phone number].

We've included an outline of the telephone interview questions, which are a part of the next phase of the study. It would be helpful if you could have your child's height and weight information available for the interview. We also have included a check request form. Please fill out the highlighted areas and return in the stamped envelope after your interview. We look forward to speaking with you.

We wish you and your family good health. Thank you again for your participation.

Sincerely,

Name of investigator or coordinator

OBJECTIVE – 2

NEXT STEP LETTER AFTER FULL SCREENING

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Date

Respondent Name
Address
City, State, Zip

Dear [Respondent Name]:

Thank you for your participation in the MRI Study of Normal Brain Development. Your time and effort in answering our questions are an important contribution to the National Institutes of Health research into children's health. We are enclosing a $20 gift certificate in appreciation.

At this time, we would like to invite you to participate in the next step in the study. In the next few weeks, one of our interviewers will call to give you the details, or you may call us directly at [phone number]. We look forward to speaking with you.

We wish you and your family good health. Thank you again for your participation.

Sincerely,

Name of investigator or coordinator

OBJECTIVE – 2

FOLLOW-UP CBCL TELEPHONE CALL
CBCL SCORED, 'OK' FOR STUDY

1. Hello. This is _____ calling from _____. May I please speak with _____?
   - **If unavailable:** When would be the best time to reach him/her? Thank you.
   - **If available:** Hello Mr/Mrs/Miss/Dr. _____. My name is _____. I'm calling on behalf of [name of PI] about the study we are conducting on brain development in healthy children. We recently received the survey and consent forms you returned. Thank you for returning them so promptly. We've sent you a $10 gift certificate from [ ] as a thank you.

2. We'd like to invite you to participate in the next phase of the study, which involves one or more telephone interviews that take from 20 to 90 minutes, depending on the interview and the family. We will send you a $10 or $20 gift certificate from [ ], depending on the amount of time we spend completing this phase of the study with you.

   Do you have any questions about the interviews or the study in general? [If NO, continue. [If YES, answer questions, then continue.]

3. Does this sound like something you'd like to do? We can schedule the first interview just about any time of day, whenever is convenient for you. [If YES, continue] [If NO, thank and end call.] Or if you like, we can complete the interview right now. [If you go ahead with interview now, be sure to review consent forms with respondent.]

4. [If not now] What day and time would be best for you?

5. We'll call to remind you about the interview the day before.

6. Thank you for your time and support.

OBJECTIVE – 2

FOLLOW-UP CBCL TELEPHONE CALL
CBCL NOT YET RECEIVED

1. Hello. This is _____ calling from _____. May I please speak with _____?
   - **If unavailable:** When would be the best time to reach him/her? Thank you.
   - **If available:** Hello Mr/Mrs/Miss/Dr. _____. My name is _____. I am calling on behalf of [name of PI] about the study we are conducting on brain development in healthy children. We recently sent you a package with study information.

2. Did you receive the package?
   - **If package not received:** The package contained a questionnaire called the Child Behavior Checklist, a consent form, and a payment form.

   - May I send you another packet? **[If NO]** Thank you for your time.

   - **[If YES]** May I confirm the address we have for you? **[Confirm address]** I will send you another packet. You should receive it within the next week. I will be calling you soon to confirm receipt of these documents.

   If package received: Have you had the opportunity to review the contents of this package?
   - **[If NO]** Okay. If it's all right with you, I'll check back in about a week to see if you have any questions.
   - **[If YES]** Do you have any questions that I can answer for you right now?

3. Do you think you would like to participate?
   - **[If NO]** Thank you for taking the time to talk to me.

   - **[If YES]** Great. We'll look for your forms in the mail. When we receive the forms from you, we'll send you a $10 gift certificate from [ ]. Thank you.

   - **[If MAYBE or DON'T KNOW]** Would you like some time to think about it? **[Or]** Could I check back with you in about a week to see if you have any more questions?

Thank you.

OBJECTIVE – 2

CALL TO SCHEDULE IN-HOUSE TESTING AND MRI

This is _____ calling from [site]. May I speak with [parent's name]? [When confirmed identity as parent] I'm calling from the MRI Study of Normal Brain Development at [site] in [city]. I would like to thank you for your participation in our study of children, and we would like to see if you are interested in continuing on the next phase of the study. Do you have a few minutes for me to tell you about it? I would like to give you some more detail about the materials we sent you earlier that describe the study.

1. [If NO] Is there a better time for me to call back?

2. [If YES] As you may recall, we're studying children and adolescents from six different cities to see how their brains work and develop. We are hoping to learn more about the typical human brain so that we can help children and adolescents with different kinds of brain disorders. We would like to have you and [child's name] come to [site] to have an MRI, a neurological/medical examination, and some tests of skills and abilities. You may recall receiving a brochure that described the MRI scan. May I tell you more about it?

> **A. (IF YES)** OK. An MRI is a way of taking detailed pictures of the brain, sort of like an X-ray, but an MRI doesn't use radiation. It is very safe. We would have your child lie on a long table that slides into a tube. He/she would lie very still in the tube and the machine would take pictures of his/her brain. We would be able to talk to him/her the entire time and he/she would be able to listen to music. You would be able to be in the room with him/her if you wanted to. We would also have him/her do some school-like testing where we would ask him/her to do all sorts of tasks such as putting together blocks and playing computer games. Doing these tasks will help us to see how different children's brains function.
>
> **B. Usually this part of the study takes about half of a day.** We compensate families in our study $_____ for their time and effort; we also pay for parking and meals during the time you are here.

Does this sound like something you might be interested in? Would you like to schedule a day and time right now? [Schedule family now if possible] [If not, offer to call back whenever convenient]. If parent says yes, ask if they have described the study to the child yet.

We are looking forward to seeing you! Do you have any questions about the things I just told you or any general questions about the study? **(Answer questions) If you have any questions before then, here is a phone number you can call _____. Thank you. (CONCLUDE CALL)**

OBJECTIVE – 2

CONFIRMATION LETTER FOR TESTING AND MRI SCAN DAY

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Dear [Parent and child name],

Thank you for participating in "The MRI Study of Normal Brain Development" at Washington University in St. Louis School of Medicine. [Child's name] is scheduled for a developmental assessment and a neurological exam on [Day of week, Date, time of day] and a MRI scan on [Day of week, Date, time of day]. Please call our office at _____ to reschedule if you cannot keep these appointments. After _____ on the evening of the MRI appointment, please call _____ if you are unable to keep the appointment.

Enclosed you will find the three Consent forms, an MRI Safety Checklist, a Family Biographical History Form, and several parent questionnaires. Please complete the consents and the other forms and return them in the enclosed envelope. The parent intending to accompany the child into the scanner should fill out the MRI Safety Checklist and the MRI Consent form. Please play the MRI sounds CD at bedtime and practice with the ear plugs so they become familiar with them.

The location for **BEHAVIOR TESTING** and the **MRI SCAN** are [specific address, including directions with building, if needed].

The developmental evaluation will take approximately ____ hours. We will be assessing your child's overall development utilizing the [name of tests the child will be taking that day]. The Neurological Exam will take an additional 30 minutes.

We remind you to dress your child, and whoever is going into the scan room, in loose, comfortable clothing, without metal trim or zippers and minimal or no makeup.

We look forward to seeing you. Please do not hesitate to call us at [phone number] if you have any questions.

Sincerely,

Site Coordinator

OBJECTIVE – 2

TELEPHONE CALL TO CONFIRM NEXT-DAY CENTER APPOINTMENT

<u>Note:</u> Before this phone call, the family should have received a packet of materials confirming the appointment time and date, providing explicit directions to the Site, and where they will be met, and any instructions for the day.

"Hi, this is _____ at _____ for the MRI Study of Normal Brain Development. I am just calling this evening to tell you how much we are looking forward to seeing _____, tomorrow! Is _____ looking forward to his/her visit with us tomorrow?

At this time, I just want to inquire if _____ has recently been sick with an illness such as a cold which might affect performance on testing tomorrow or make it hard to be still for the MRI?"

If the answer is "No":

"Great! We will see you tomorrow at _____ A.M./P.M. Have a good night tonight and a safe trip into the Medical Center tomorrow. Do you have any questions about how to find us or where to park? Please call us at [insert phone number] if you have any problems tomorrow."

If the answer is "Yes":

"Oh, I am sorry to hear that. It would be best if we re-scheduled _____ evaluation for sometime in the next 1-3 weeks when he/she is likely to feel much better. Would that be all right?"

OBJECTIVE – 2

THANK YOU LETTER

Date

Respondent Name
Address
City, State, Zip

Dear [Respondent Name]:

Thank you for participating in the MRI Study of Normal Brain Development at [site]. Your time and effort are very much appreciated! Your participation has made a significant contribution to increasing our understanding of children's physical and mental development.

If you have any questions, please feel free to give us a call at [phone number]. We'd like to stay in touch with you as our study continues, and to send you regular newsletters. If you move or change your phone number, we'd appreciate a call--please call [coordinator] at [phone number]. Thanks.

Sincerely,

Principal Investigator or Coordinator

OBJECTIVE – 2

MISSING PARENT FORMS

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Date

Respondent Name
Address
City, State, Zip

Dear [Respondent Name]:

Thank you for participating in The MRI Study of Normal Brain Development at _____ _____. Enclosed are parent forms for [child's name] last visit. Please complete them and return them in the enclosed stamped, self-addressed envelope.

We look forward to seeing you in a couple of months. Please do not hesitate to call us at [phone number].

Thank you again for your participation.

Sincerely,

Site Investigator or Coordinator

OBJECTIVE – 2

UNRETURNED PHONE MESSAGES LETTER

Date

Respondent Name
Address
City, State, Zip

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Dear [Respondent Name]:

Thank you for your participation in the MRI Study of Normal Brain Development. We are hoping to continue your participation by bringing [Child's name] in again for testing and an MRI.

We have been unable to reach you directly by phone, though we have left messages. We would like to speak to you to (re)schedule [Child's Name] day of visit. Please give us a call at [phone number] to schedule a time for your visit or let us know a good time to call you. It is very important [child's name] is seen in a specific time frame based on physical, mental, and emotional growth since his/her last visit.

We wish you and your family good health. Thank you again for your participation.

Sincerely,

Site Investigator or Coordinator

OBJECTIVE – 2

FINAL LETTER: STUDY COMPLETION

Date

Respondent Name
Address
City, State, Zip

The MRI study of normal brain development
Sponsored by the National Institutes of Health

Dear [Respondent Name],

Thank you for participating in The MRI Study of Normal Brain Development. Your participation has made a significant contribution to increasing our understanding of children's physical and mental development. Your time and effort are very much appreciated!

We have acquired a full set of scans for [Child's Name]. At this time we do not anticipate scanning [Child's Name] further. As our study continues, we would like to stay in touch with you by sending updates of the study. If you move or change your phone number, please notify us.

If there is anything that we can do for you in the future, please do not hesitate to call us at [phone number]. We wish you and your family good health. Thank you again for your participation.

Sincerely,

Name of Investigator or Coordinator

OBJECTIVE – 2

BIRTHDAY CARD

Happy Birthday [Child's Name]!

Thank you for your participation
helping kids of every nation
with your time and concentration,
perspiration and motivation.

We have begun the realization
of the brain exploration,
the start of an expedition
expanding our imagination.

Happy Birthday! Congratulations!
We share in your jubilation!
You have our deepest admiration!
You are a true inspiration!

We appreciate your continuation
aiding research and innovation!
(Please call us with no hesitation
if you'd like more information!)

From your friends at [Center]
[Names] (Phone)

The MRI Study of Normal Brain Development

at [Site]

www.brain-child.org

NIMH National Institute of Mental Health

National Institute of Child Health and Human Development

National Institute of Neurological Disorders and Stroke

SAMPLE NEWSLETTER

Summer 2005 Volume 1 Number 1

MRI Study of Normal Brain Development Newsletter

EXTRA!! EXTRA!! READ ALL ABOUT IT!

The MRI Study of Normal Brain Development has completed its third year of recruitment! We cannot emphasize enough how much we value your participation in this study. Thank you boys and girls for your excellent work during your visit with us and especially your sound sleeping during the MRI! We would also like to thank the mothers, fathers, and grandparents for all the time and commitment they have contributed to the success of this study.

You are making an important and unique contribution to what is currently known about child brain development. The purpose of our study is to learn more about brain development in typical healthy children and to provide a comparison point for children who have childhood brain disorders, such as epilepsy, autism, or mental retardation.

Our sample currently includes 75 children, 39 boys and 36 girls who have all completed at least one successful scan and developmental testing at Boston Children's Hospital or in St. Louis at Washington University. Many of you have completed multiple visits for developmental testing and MRI brain scan. Over the next three years, our goal is to recruit an additional 100 children between the ages of birth through 4 ½ years of age.

This study will provide the most comprehensive knowledge of early human brain development that has ever been achieved! This enhanced understanding of the development of the human brain will provide a template of the brain so that it will allow for the accurate detection of brain injuries and abnormalities in children from birth to 18 years of age. Additionally, a database is being created for doctors and researchers all over the world to help other boys and girls with brain disorders or developmental problems. (Remember that we will protect your confidentially so no one who uses the database will know your identity.)

Planning to Move?

If you plan to move or if you change phone numbers, please be sure to contact us (See telephone number). We will be sending out birthday cards and study updates periodically. And of course scheduling your next visit and sending out questionnaires about how your child is progressing. Thanks!

The ABC's

For many of you your next visit is around the corner. Here are just a few reminders.

Always:

- Play the MRI sound tape/CD to allow your child to become familiar with the sound, so that if the child wakes up during the scan they are not frightened by the noise.
- Practice with the earplugs helps the child became familiar with the sensation of having something in their ears.

Bring:

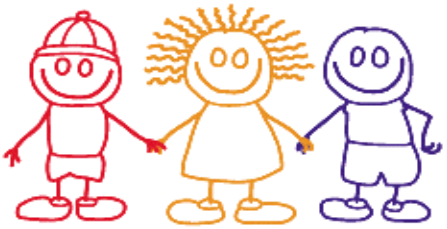
- A warm sweatshirt because it is cold in the MRI room.
- Your child can bring their blanket or stuffed animal to keep them company in the scanner and to help them get to sleep.

Collect:

- Weigh-your child, if your child's scan is before their behavioral testing.
- Consents and parent forms.

If you have any questions, please do not hesitate to contact our study line: Dr. C. Robert Almli's study line: (314) 286-1645 (contact: Tina Day)

We also invite you and your child to visit our internet website at http://www.brain-child.org



OBJECTIVE – 2

INTERVIEW / PARENT FORMS PROCEDURES

FAMILY INTERVIEWS FOR GENETIC STUDIES (FIGS-MRI)

PARENTING STRESS INDEX (PSI)

CAREY TEMPERAMENT SCALES (CTS)

CHILD BEHAVIOR CHECKLIST (CBCL)

FAMILY BIOGRAPHICAL HISTORY FORM

OBJECTIVE – 2

FAMILY INTERVIEWS FOR GENETIC STUDIES – MRI

AGES: 0:0 – 4:5

Initiative NSaBDG, 1992. Family interview for genetic studies. Bethesda, National Institute of Mental Health, Molecular Genetics Initiative.

Maxwell, E.M., 1992. Manual for the FIGS. Retrieved from: http://zork.wustl.edu/nimh/digs/newpage11.htm.

-!!!SCREENING TEST!!!-

Exclusion Criteria:

Family excluded if parent or full sibling is found to have any of the following Axis I psychiatric disorders: schizophrenia, bipolar disorder, psychotic disorder, alcoholism, OCD, Tourette disorder, recurrent major depression, ADHD, and/or PDD.

MATERIALS

- FIGS interview packet
- Blank paper
- Pencil
- General Screening Question Forms
- Extra face sheets for each family member
- FIGS checklists
  - Depression checklist
  - Mania checklist
  - Psychosis checklist
  - Alcohol, nicotine & drug abuse checklist
  - Paranoid/Schizoid/Schizotypal Personality and Pervasive Developmental Disorder checklist
  - Antisocial Personality Disorder checklist
  - TIC disorder checklist
  - Obsessive Compulsive Disorder checklist
  - Attention Deficit/Hyperactivity Disorder checklist

GENERAL INSTRUCTIONS

1. Before you begin the FIGS you will need to make a pedigree.
A detailed pedigree provides the following for each person: name, sex, age at the time of pedigree drawing, marital status, role in the family, whether living or dead, and if dead, age at the time of death.

The pedigree should include all first-degree relatives **to the child.** Therefore, the pedigree includes the child, biological siblings (living and dead), and biological parents.

2. Ask the General Screening Questions.

Ask the informant to keep in mind all of the relatives in the pedigree as he/she listens to the questions you will read. When you get a positive response to one of the questions, record it directly on the pedigree by the name of the person being described. (You may also indicate positives on the screening sheet.) At this point you are receiving overall, general information and writing notes on the pedigree, being careful to pick up any hints of pathology. Probing for more detail can come later with the Face Sheets and symptom checklists.

3. Ask about individual relatives, using a Face Sheet and symptom checklists.

Having completed the General Screening Questions and having noted the responses directly on the pedigree, complete a Face Sheet for each of the child's first-degree relatives. Ask about each one, using a separate Face Sheet for each, whether or not there is any hint of pathology reported by the informant.

Write on the Face Sheet any narrative that may have significance for diagnosis. The narrative can be one or two sentences describing any psychiatric or personality problems. If the informant offers nothing and you feel it would help, you could do some prompting from the General Screening Questions to refresh his/her memory on what information is being sought, at your own discretion.

If there is any known pathology, you should have detected it while going through the General Screening Questions with the pedigree. As you do a Face Sheet, immediately examine those hints and complete pertinent checklists that were indicated by the screening questions. The checklists ask details of symptoms, number of episodes, duration, age of onset, treatment, and impairment rating. Complete a symptom checklist for any suspected depression, mania, alcohol or drug abuse, psychosis, or paranoid/schizoid/schizotypal personality.

Should you learn of a disorder other than those for which there are checklists, go to the Face Sheet, which allows space for a description of disorders which were not specifically covered and has questions on the age of onset, treatment, and impairment.

If you start a checklist and find the informant cannot provide details stop using the checklist. If you are unsure about whether a family member has met a positive diagnosis, continue to complete all appropriate checklists and face sheets on all family members and review with your supervisor or site coordinator.

The Family Interview for Genetic Studies (FIGS) allows for the systematic collection of psychiatric history about a subject's family. The FIGS is administered in three parts:

1. First, a family pedigree is drawn (see pedigree codes).
2. Second, the General Screening Questions are administered. The subject is asked to answer the question for all persons on the pedigree, excluding the child of interest.
3. Finally, a Face Sheet for each member of the family pedigree **and** applicable checklists should be completed.

The Family Interview for Genetic Stuides (FIGS) has been revised for the MRI Study of Normal Brain Development by Richard D. Todd, Ph.D., M.D.; Kelly N. Botteron, M.D.; Tisha Singer, B.A.; and Karla Smith, B.S.. Revised items include the addition of screening questions and symptom checklists for attention deficit/hyperactivity disorder, Tourrette's Syndrome, pervasive developmental disorders (autism), obsessive compulsive disorder and antisocial personality disorder. The alcohol and drug

abuse section was expanded to include nicotine and additional modifications in identification/labeling of face sheets.

The Instruction Manual for the FIGS can be obtained from (http://zork.wustl.edu/nimh/figs/figs_train.pdf). The FIGS interview can be obtained from (http://zork.wustl.edu/nimh/figs/FIGS.pdf). The FIGS as modified for the MRI Study of Normal Brain Development can be obtained from (http://www.bic.mni.mcgill.ca/nihpd/Study_materials/Subject_binders/sub_bind_obj1/V2_FIGS_Feb23_05.pdf)

RELATIONSHIP CODES	**ALL CODES ARE IN RELATIONSHIP TO THE CHILD OF INTEREST**	***If more codes are needed….***
FB1	Full Brother	Continue with FB2, FS2, etc., as needed for additional full siblings. Assign labels in order from oldest to youngest.
FS1	Full Sister	
HB1	Half Brother	Step-siblings can be included on the pedigree, especially if they live in the home of the child of interest. However, they are not included in the FIGS interview itself, unless 2nd degree relatives are included.
HS1	Half Sister	
MOM	Biological Mother	Step-parents can be included on the pedigree, especially if they live in the home of the child of interest. However, they are not included in the FIGS interview itself.
DAD	Biological Father	
CID1	Child of Interest's Daughter	Child born of child of interest. Not used in Objective-2.
CIS1	Child of Interest's Son	
MA1	Full Maternal Aunt	Only full aunts, uncles, and grandparents will be included in the FIGS interview including second degree relatives.
MU1	Full Maternal Uncle	
PA1	Full Paternal Aunt	
PU1	Full Paternal Uncle	
MGM	Maternal Grandmother	
MGF	Maternal Grandfather	
PGM	Paternal Grandmother	
PGF	Paternal Grandfather	

OBJECTIVE – 2

PARENTING STRESS INDEX (PSI)

AGES 0:3 – 4:5

Abidin, R.R., 1995. Parenting Stress Index, 3rd ed. Psychological Assessment Resources, Inc., Odessa.

FOLLOW PSI ADMINISTRATION AND SCORING PROCEDURES PROCEDURES

UPLOAD SCORES TO THE DATABASE!

OBJECTIVE – 2

CAREY TEMPERAMENT SCALES
0:3 – 4:5

Medoff-Cooper, B., Carey, W.B., McDevitt, S.C., 1995. The Carey Temperament Scales. Behavioral-Development Initiatives, Scottsdale.

Early Infant Temperament Questionnaire (EITQ) 0:1 – 0:3
Revised Infancy Temperament Questionnaire (RITQ) 0:4 – 0:11
Toddler Temperament Scale (TTS) 1:0 – 2:11
Behavioral Style Questionnaire (BSQ) 3:0 – 4:5

FOLLOW CAREY TEMPERAMENT ADMINISTRATION AND SCORING INSTRUCTIONS

UPLOAD SCORES TO THE DATABASE!

OBJECTIVE – 2

CHILD BEHAVIOR CHECKLIST (CBCL 1.5-5)

AGES 1:6 – 4:5

Achenbach, T.M., Rescorla, L.A., 2000. Manual for the ASEBA Preschool Forms & Profiles. University of Vermont Department of Psychiatry, Burlington.

-!!!SCREENING TEST!!!-
Exclusion Criteria:
CBCL Score > 70 On Any Problem Scale
Mean = 50, SD = 10

FOLLOW CBCL ADMINISTRATION AND SCORING INSTRUCTIONS

UPLOAD SCORES TO THE DATABASE!

OBJECTIVE – 2

FAMILY BIOGRAPHICAL HISTORY FORM
AGES: 0:0 - 4:5

Instructions: Please complete the following spaces and questions about your child who is participating in this study and that child's biological mother and father. Note that some of the items may not apply to the child named below or your family. For those items, put "NA" in the spaces provided. For the initial (1st) test and scan, fill in **all** items. For subsequent (e.g., 2nd, 3rd) tests/scans, update only the **white (non-shaded) items** (Be sure to date [yyyy/mm/dd] each update). If you have questions about any of the items, please call us at _____. Thank you.

Your Name:_____

Your relationship to the Child named below: Mother Father Other:_____

Child's name:_____ **Child's Date of Birth:**_____/____/_____
yyyy mm dd

Child's Gender: Male Female

I. PARENT, CHILD AND FAMILY INFORMATION

A. BIOLOGICAL MOTHER

Date of Birth:_____/_____/_____ Current Age: _____Years
yyyy mm dd

Hand Preference: RIGHT LEFT NO PREFERENCE

Ethnicity Hispanic or Latino _____ Not Hispanic or Latino _____

Race
American Indian or Alaska Native _____
African American or Black _____
Asian _____
Native Hawaiian or Other Pacific Islander _____
White _____

Education
High School Degree: YES NO or Grade Completed _____
College Degree: YES NO or Years Completed _____
Post-Graduate Degree YES NO or Years Completed_____

Current Marital Status: SINGLE MARRIED WIDOWED DIVORCED

Occupation/Job Title:_____

B. BIOLOGICAL FATHER

Date of Birth:_____/_____/_____ Current Age: _____Years
yyyy mm dd

Father's age at birth of the child:_____years

Hand Preference: RIGHT LEFT NO PREFERENCE

Ethnicity Hispanic or Latino _____ Not Hispanic or Latino _____

Race
American Indian or Alaska Native _____
African American or Black _____
Asian _____
Native Hawaiian or Other Pacific Islander _____
White _____

Education
High School Degree: YES NO or Grade Completed _____
College Degree: YES NO or Years Completed _____
Post-Graduate Degree YES NO or Years Completed_____

Current Marital Status: SINGLE MARRIED WIDOWED DIVORCED

Occupation/Job Title:_____

C. THE CHILD BEING STUDIED

Hand Preference: RIGHT LEFT NO PREFERENCE

Ethnicity Hispanic or Latino _____ Not Hispanic or Latino _____

Race
American Indian or Alaska Native _____
African American or Black _____
Asian _____
Native Hawaiian or Other Pacific Islander _____
White _____

D. THE FAMILY

Child Lives with:
Biological Mother _____
Biological Father _____
Step Mother _____
Step Father _____
Other _____

Zip Code (child's home): _____

Total Household Income:

- _____ zero to $5,000
- _____ $5,001 to $10,000
- _____ $10,001 to $15,000
- _____ $15,001 to $25,000
- _____ $25,001 to $35,000
- _____ $35,001 to $50,000
- _____ $50,001 to $75,000
- _____ $75,001 to $100,000
- _____ $100,001 to 150,000
- _____ Over $150,000

For each of the child's siblings, indicate DATE OF BIRTH (DOB), GENDER, HAND USED FOR WRITING, and if ENGLISH IS SPOKEN AT HOME.

Please also indicate if siblings of 'The Child' are Full Siblings [F] (have same biological parents as 'The Child'), Half Siblings [H] (share one biological parent with 'The Child'), or are Adopted Siblings [A] (do not share any biological parent with 'The Child').

DOB	F-H-A	GENDER		HAND USED FOR WRITING			ENGLISH AT HOME	
______ yyyy/mm/dd	F H A	M	F	RIGHT	LEFT	NO PREFERENCE	YES	NO
______ yyyy/mm/dd	F H A	M	F	RIGHT	LEFT	NO PREFERENCE	YES	NO
______ yyyy/mm/dd	F H A	M	F	RIGHT	LEFT	NO PREFERENCE	YES	NO
______ yyyy/mm/dd	F H A	M	F	RIGHT	LEFT	NO PREFERENCE	YES	NO
______ yyyy/mm/dd	F H A	M	F	RIGHT	LEFT	NO PREFERENCE	YES	NO
______ yyyy/mm/dd	F H A	M	F	RIGHT	LEFT	NO PREFERENCE	YES	NO
______ yyyy/mm/dd	F H A	M	F	RIGHT	LEFT	NO PREFERENCE	YES	NO

Other people living in the child's home (not counting the mother, father, and siblings):

DOB	GENDER		RELATIONSHIP TO CHILD	ENGLISH AT HOME	
________ yyyy/mm/dd	M	F	______________________	YES	NO
________ yyyy/mm/dd	M	F	______________________	YES	NO
________ yyyy/mm/dd	M	F	______________________	YES	NO
________ yyyy/mm/dd	M	F	______________________	YES	NO

Total Number of Dependents "plus" Head of Household (as per tax declaration):________

For example: father + mother + 3 children = '5'

II. PREGNANCY, BIRTH AND NEONATAL PERIOD OF THE CHILD

A. WHILE PREGNANT WITH THE CHILD

1. Name the medications (over-the-counter or prescription) taken by the mother while pregnant with the child, and **indicate how long used**:

Prenatal Vitamins:_____
e.g., Nestabs, Materna, Natalins, Natabec
Pre-term Labor Medications:_____
e.g., Terbutaline
Antihistimines:_____
e.g. Tylenol Cold, Benadryl
Antacids:_____
e.g., Tums, Rolaids, Gaviscon, Pepsid, Zantac
Antibiotics:_____
e.g., Penicillin, Amoxicillin, Ceclor
Pain Medications:_____
e.g., Advil, Tylenol, Motrin, Naprosyn
Herbal Supplements:_____
e.g., Ginkgo biloba, St. John's wort
Other Medications:_____

B. BIRTH OF THE CHILD

1. Was child born in a hospital? YES NO

If NO, where was the child born? _____

2. Was labor Induced? YES NO

If YES, **give induction method and reason for induction**: _____

_____

3. How many days did the MOTHER (_____days) and the CHILD (_____days) spend in the hospital following delivery?
If more than 3-days, **please explain the circumstances**: _____

C. CHILD'S BREAST FEEDING HISTORY

1. Did the mother Breast Feed the child? YES NO
(If 'YES', then answer Questions 2-6 below, otherwise, skip to 'III' below)

2. How long was Breast Milk the only source of the child's nutrition, that is, no supplemental formula or solid food?
   Child Age at start of breast milk feeding:
   _____days _____weeks _____months _____years
   Child Age when first supplemented with formula and/or solid food:
   _____ days _____weeks _____months _____years

3a. Is the child still receiving Breast Milk feedings? YES NO

If "NO", Respond to 3b

3b. How old was the child when the child received the last (final) Breast Milk feeding?

Child Age at last Breast Milk feeding: _____ days _____weeks _____months _____years

4. Did the child's mother ever smoke while the child was on Breast Milk? YES NO
   If YES, how many cigarettes were smoked per week? _____ cigarettes/week

5. Did the child's mother ever drink alcohol while the child was on Breast Milk? YES NO
   If YES, then how many drinks were consumed per week? _____drinks/week

6. Did the child's mother use any medications (over-the-counter or prescription) while the child was on Breast Milk? YES NO
   If YES, **name the medications and indicate how long used**:

   Vitamins:_____

   Antibiotics:_____

   Antacids:_____

   Antihistamines (e.g., Benadryl):_____

   Painkillers (e.g., Tylenol, Ibuprofen): _____

   Other (Including Herbal):_____

III. EXPERIENCES OF THE CHILD DURING DEVELOPMENT

1. Has the child had 'EAR TUBES' placed? YES NO
   If YES, age of child when ear tubes were placed:
   _____ days _____weeks _____months _____years

2. Has the child had GENERAL ANESTHESIA? YES NO
   If YES, age of child at time anesthesia was given:
   _____ days _____weeks _____months _____years

3. Has the child received a blood test to check lead levels? YES NO
   If YES, age of child at screening:
   _____ days _____weeks _____months _____years
   If YES, was the lead level: HIGH MARGINAL NORMAL(LOW) UNKOWN

4. Has the child ever "hit their head" (e.g., falling down stairs, hit on head by object, fall off bike, etc.) seriously enough that a physician, clinic, or hospital was contacted or visited? YES NO

   Number of occurrences:_____

   Describe the head injury event(s): How injured, diagnosis (e.g., concussion), any treatment, and the child's age (___days ___weeks ___months ___years) for each event:

   _____

   _____

   _____

5. Has the child ever been diagnosed with STREP THROAT? YES NO
   If YES, '1-2 TIMES' '3-5 TIMES' '6 OR MORE TIMES'

6. Has the child participated in any type of 'Child Care' program? YES NO
   If YES, indicate: Baby Sitter Day Care Other:_____
   On average, how many days per week:_____

7. Has the child participated in Parents as Teachers, Head Start, or any other type of PreSchool program? YES NO
   If YES, circle the appropriate program above or List:_____

8. Has the child attended a formal School Program (e.g., Kindergarten)? YES NO

9. Has the child participated in Organized Sports (T-Ball, Soccer)? YES NO

10. Has the child had any Music Training or Lessons? YES NO

OBJECTIVE – 2

PROCEDURES FOR SCANS AND BEHAVIORAL TESTING

TEST BATTERY BY TARGET AGE

LISTING OF PARENT FORMS AND CHILD TESTS

PROCEDURES CHECKLIST

IN-HOUSE PROCEDURES (CHILD)

OBJECTIVE – 2

TEST BATTERY BY TARGET AGE

Targeted Test Age in months	BSID-MDI & BRS	BSID-PDI	PLS-3	CBCL	PURDUE	NEPSY	CANTAB	Neuro Exam	Carey Temperament Scales	Handedness	DAS
NB								0:0 - 0:1			
3	√	√	√					0:2 - 0:11	Early Infant Temperament		
6	√	√	√					0:2 - 0:11	Revised Infancy Temperament		
9	√	√	√					0:2 - 0:11	Revised Infancy Temperament		
12	√	√	√					1:0 - 2:11	Toddler Temperament	1:0-2:11	
15	√	√	√					1:0 - 2:11	Toddler Temperament	1:0-2:11	
18	√	√	√	√				1:0 - 2:11	Toddler Temperament	1:0-2:11	
24	√	√	√	√				1:0 - 2:11	Toddler Temperament	1:0-2:11	
30	√	√	√	√				1:0 - 2:11	Toddler Temperament	1:0-2:11	
36		√	√	√	√	√		3:0 - 4:5	Behavioral Style	3:0 - 4:5	Lower Preschool
48			√	√	√	√	√	3:0 - 4:5	Behavioral Style	3:0 - 4:5	Upper Preschool

OBJECTIVE – 2

LISTING OF PARENT FORMS AND CHILD TESTS

AGES: 0:0 - 4:5

Items in **Bold** are Exclusionary

BIRTH / NEONATAL (0:0)

10-14 DAYS POST-EDC

PARENT INTERVIEWS

1. **Screening & Exclusion Form (All Ages)**

2. **Family Interview for Genetic Studies (FIGS: All Ages)**

PARENT FORMS:

1. **Scan-Testing Biographical Form (All Ages)**

2. Family Biographical History Form (All Ages)

CHILD TESTS:

1. **Neurological Examination / 0:0 - 0:1**
   Neuro Exam at 10-14 days post-EDC

2. **MRI** & DTI
   Brain Scan at 10-14 days post-EDC

3. MRS & MRSI (Ancillary A sites only)

3 MONTHS (0:3)

PARENT INTERVIEWS

1. **Screening & Exclusion Form (All Ages)**

2. **Family Interview for Genetic Studies (FIGS: All Ages)**

PARENT FORMS:

1. **Scan-Testing Biographical Form (All Ages)**

2. Carey Temperament/Early Infant Temperament Questionnaire (EITQ: 0:1 to 0:3)

3. Parent Stress Index (PSI: 0:1 to 12:0)

4. Family Biographical History Form (All Ages)

CHILD TESTS:

1. **Bayley Scales of Infant Development II (BSID-II: 0:1 to 3:6)**
    a. **Mental Developmental Scale/Index (MDI)**
    b. **Psychomotor Developmental Scale/Index (PDI)**
    c. Behavior Rating Scale (BRS)

2. **Preschool Language Scale-3 (PLS-3: Birth to 6:11)**

3. **Neurological Examination 0:2 - 0:11**

4. **MRI** & DTI

5. MRS & MRSI (Ancillary A sites only)

6 & 9 MONTHS (0:6-0:9)

PARENT INTERVIEWS

1. **Screening & Exclusion Form (All Ages)**

2. **Family Interview for Genetic Studies (FIGS: All Ages)**

PARENT FORMS:

1. **Scan-Testing Biographical Form (All Ages)**

2. Carey Temperament / Revised Infant Temperament Questionnaire (RITQ: 0:4 to 0:11)

3. Parent Stress Index (PSI: 0:1 to 12:0)

4. Family Biographical History Form (All Ages)

CHILD TESTS:

1. **Bayley Scales of Infant Development II (BSID-II: 0:1 to 3:6)**
    a. **Mental Developmental Scale/Index (MDI)**
    b. **Psychomotor Developmental Scale/Index (PDI)**
    c. Behavior Rating Scale (BRS)

2. **Preschool Language Scale-3 (PLS-3: Birth to 6:11)**

3. **Neurological Examination / 0:2 - 0:11**

4. **MRI** & DTI

5. MRS & MRSI (Ancillary A sites only)

12 & 15 MONTHS (0:12-0:15)

PARENT INTERVIEWS

1. **Screening & Exclusion Form (All Ages)**

2. **Family Interview for Genetic Studies (FIGS: All Ages)**

PARENT FORMS:

1. **Scan-Testing Biographical Form (All Ages)**

2. Carey Temperament / Toddler Temperament Scale (TTS: 1:0 to 2:11)

3. Parent Stress Index (PSI: 0:1 to 12:0)

4. Family Biographical History Form (All Ages)

CHILD TESTS:

1. **Bayley Scales of Infant Development II (BSID-II: 0:1 to 3:6)**
    a. **Mental Developmental Scale/Index (MDI)**
    b. **Psychomotor Developmental Scale/Index (PDI)**
    c. Behavior Rating Scale (BRS)

2. **Preschool Language Scale-3 (PLS-3: Birth to 6:11)**

3. **Neurological Examination / 1:0 - 2:11**

4. Handedness / 1:0 - 2:11

5. **MRI** & DTI

6. MRS & MRSI (Ancillary A sites only)

18, 24 & 30 MONTHS (0:18-0:30)

PARENT INTERVIEWS

1. **Screening & Exclusion Form (All Ages)**

2. **Family Interview for Genetic Studies (FIGS: All Ages)**

PARENT FORMS:

1. **Scan-Testing Biographical Form (All Ages)**

2. **Child Behavior Checklist / 1.5 - 5 Years Old (CBCL: 1:6 to 5:0)**

3. Carey Temperament / Toddler Temperament Scale (TTS: 1:0 to 2:11)

4. Parent Stress Index (PSI: 0:1 to 12:0)

5. Family Biographical History Form (All Ages)

CHILD TESTS:

1. **Bayley Scales of Infant Development II (BSID-II: 0:1 to 3:6)**
    a. **Mental Developmental Scale/Index (MDI)**
    b. **Psychomotor Developmental Scale/Index (PDI)**
    c. Behavior Rating Scale (BRS)

2. **Preschool Language Scale-3 (PLS-3: Birth to 6:11)**

3. **Neurological Examination / 1:0 - 2:11**

4. Handedness / 1:0 - 2:11

5. **MRI** & DTI

6. MRS & MRSI (Ancillary A sites only)

36 MONTHS (0:36)

PARENT INTERVIEWS

1. **Screening & Exclusion Form (All Ages)**

2. **Family Interview for Genetic Studies (FIGS: All Ages)**

PARENT FORMS:

1. **Scan-Testing Biographical Form (All Ages)**

2. **Child Behavior Checklist / 1.5 - 5 Years Old (CBCL: 1:6 to 5:0)**

3. Carey Temperament / Behavioral Style Questionnaire (BSQ: 3:0 to 4:5)

4. Parent Stress Index (PSI: 0:1 to 12:0)

5. Family Biographical History Form (All Ages)

CHILD TESTS:

1. **Bayley Scales of Infant Development II (BSID-II: 0:1 to 3:6)**
   Psychomotor Developmental Scale/Index (PDI) only

2. **Differential Ability Scale-Preschool (DAS: 2:6 to 17:11)**

3. **Preschool Language Scale-3 (PLS-3: Birth to 6:11)**

4. **Neurological Examination / 3:0 – 4:5**

5. Handedness (Eye & Foot) / 3:0 - 4:5

6. Purdue Pegboard--Half-Board / 3:0 - 4:5

7. NEPSY--Semantic Verbal Fluency / 3:0 - 4:5 (Semantic: 3:0 to 18+yrs)

8. **MRI** & DTI

9. MRS & MRSI (Ancillary A sites only)

48 MONTHS (0:48)

PARENT INTERVIEWS

1. **Screening & Exclusion Form (All Ages)**

2. **Family Interview for Genetic Studies (FIGS: All Ages)**

PARENT FORMS:

1. **Scan-Testing Biographical Form (All Ages)**

2. **Child Behavior Checklist / 1.5 - 5 Years Old (CBCL: 1:6 to 5:0)**

3. Carey Temperament / Behavioral Style Questionnaire (BSQ: 3:0 to 4:5)

4. Parent Stress Index (PSI: 0:1 to 12:0)

5. Family Biographical History Form (All Ages)

CHILD TESTS:

1. **Differential Ability Scale-Preschool (DAS: 2:6 to 17:11)**

2. **Preschool Language Scale-3 (PLS-3: Birth to 6:11)**

3. **Neurological Examination / 3:0 – 4:5**

4. Handedness (Eye & Foot) / 3:0 - 4:5

5. Cambridge Neuropsychological Test Automated Battery (CANTAB: 4:0 - 4:5)
    a. Motor Screening
    b. Big Little Circle
    c. Spatial Span
    d. Spatial Working Memory
    e. Intra / Extra Dimensional Shift Task

6. Purdue Pegboard--Half-Board / 3:0 - 4:5

7. NEPSY--Semantic Verbal Fluency / 3:0 - 4:5 (Semantic: 3:0 to 18+yrs)

8. **MRI** & DTI

9. MRS & MRSI (Ancillary A sites only)

OBJECTIVE – 2

PROCEDURES CHECKLIST: NEWBORNS ("10-14 DAYS Post –EDC")

Procedure	Administered/ Sent	Hand Scored or Filled Out	Entered into Web Database/Laptop	Exported and Uploaded to DCC (Laptop
CONTACT SHEET				
CONSENT & ASSENT FORMS				
EXCLUSION CHECKLIST				
FAMILY BIOGRAPHICAL HISTORY FORM				
DEMOGRAPHICS				
FAMILY INTERVIEW FOR GENETIC STUDIES (FIGS)				
SCAN-TESTING BIOGRAPHICAL FORM				
NEUROLOGICAL EXAM / 0:0-0:1				
MRI SAFETY FORM				
MRI & MR TECHNOLOGIST'S FORM				
COORDINATOR REPORT FORM				
PAYMENT FORMS				

OBJECTIVE – 2

PROCEDURES CHECKLIST: 3 MONTHS

Procedure	Administered/ Sent	Hand Scored or Filled Out	Entered into Web Database/Laptop	Exported and Uploaded to DCC (Laptop
CONTACT SHEET				
CONSENT & ASSENT FORMS				
EXCLUSION CHECKLIST				
FAMILY BIOGRAPHICAL HISTORY FORM				
DEMOGRAPHICS				
FAMILY INTERVIEW FOR GENETIC STUDIES (FIGS)				
SCAN-TESTING BIOGRAPHICAL FORM				
Preschool Language Scale-3				
Bayley Scales of Infant Development II: Mental, Motor and BRS				
NEUROLOGICAL EXAM / 0:2-0:11				
Parenting Stress Index: Parent Form and Computer Printout			L	
Carey Temperament/[EITQ: 0:1 to 0:3]				
MRI SAFETY FORM				
MRI & MR TECHNOLOGIST'S FORM				
COORDINATOR REPORT FORM				
PAYMENT FORM				

OBJECTIVE – 2

PROCEDURES CHECKLIST: 6 AND 9 MONTHS

Procedure	Administered/ Sent	Hand Scored or Filled Out	Entered into Web Database/Laptop	Exported and Uploaded to DCC (Laptop
CONTACT SHEET				
CONSENT & ASSENT FORMS				
EXCLUSION CHECKLIST				
FAMILY BIOGRAPHICAL HISTORY FORM				
DEMOGRAPHICS				
FAMILY INTERVIEW FOR GENETIC STUDIES (FIGS)				
SCAN-TESTING BIOGRAPHICAL FORM				
Preschool Language Scale-3				
Bayley Scales of Infant Development II: Mental, Motor and BRS				
NEUROLOGICAL EXAM / 0:2-0:11				
Parenting Stress Index: Parent Form and Computer Printout			L	
Carey Temperament/ [RITQ 0:4-0:11]				
MRI SAFETY FORM				
MRI & MR TECHNOLOGIST'S FORM				
COORDINATOR REPORT FORM				
PAYMENT FORMS				

OBJECTIVE – 2

PROCEDURES CHECKLIST: 12 AND 15 MONTHS

Procedure	Administered/ Sent	Hand Scored or Filled Out	Entered into Web Database/Laptop	Exported and Uploaded to DCC (Laptop Only)
CONTACT SHEET				
CONSENT & ASSENT FORMS				
EXCLUSION CHECKLIST				
FAMILY BIOGRAPHICAL HISTORY FORM				
DEMOGRAPHICS				
FAMILY INTERVIEW FOR GENETIC STUDIES (FIGS)				
SCAN-TESTING BIOGRAPHICAL FORM				
Preschool Language Scale-3				
Bayley Scales of Infant Development II: Mental, Motor and BRS				
Handedness / 1:0-2:11				
NEUROLOGICAL EXAM / 1:0-2:11				
Parenting Stress Index: Parent Form and Computer Printout			L	
Carey Temperament/ [TTS 1:0-2:11]				
MRI SAFETY FORM				
MRI & MR TECHNOLOGIST'S FORM				
COORDINATOR REPORT FORM				
PAYMENT FORMS				

OBJECTIVE – 2

PROCEDURES CHECKLIST: 18, 24, AND 30 MONTHS

Procedure	Administered/ Sent	Hand Scored or Filled Out	Entered into Web Database/Laptop	Exported and Uploaded to DCC (Laptop Only)
CONTACT SHEET				
CONSENT & ASSENT FORMS				
EXCLUSION CHECKLIST				
FAMILY BIOGRAPHICAL HISTORY FORM				
DEOMGRAPHICS				
FAMILY INTERVIEW FOR GENETIC STUDIES (FIGS)				
SCAN-TESTING BIOGRAPHICAL FORM				
Preschool Language Scale-3				
Bayley Scales of Infant Development II: Mental, Motor and BRS				
Handedness / 1:0-2:11				
NEUROLOGICAL EXAM / 1:0-2:11				
Parenting Stress Index: Parent Form and Computer Printout			L	
Carey Temperament/ [TTS 1:0-2:11]				
Child Behavior Checklist Parent Form & Computer Printout			L	
MRI SAFETY FORM				
MRI & MR TECHNOLOGIST'S FORM				
COORDINATOR REPORT FORM				
PAYMENT FORMS				

OBJECTIVE – 2

PROCEDURES CHECKLIST: 36 MONTHS

Procedure	Administered/ Sent	Hand Scored or Filled Out	Entered into Web Database/Laptop	Exported and Uploaded to DCC (Laptop Only)
CONTACT SHEET				
CONSENT & ASSENT FORMS				
EXCLUSION CHECKLIST				
FAMILY BIOGRAPHICAL HISTORY FORM				
DEMOGRAPHICS				
FAMILY INTERVIEW FOR GENETIC STUDIES (FIGS)				
SCAN-TESTING BIOGRAPHICAL FORM				
Preschool Language Scale-3				
Bayley Scales of Infant Development II: Motor Scale Only				
Differential Ability Scale: Preschool Form & Computer Printout			W L	
Handedness (eye & foot) / 3:0-4:5				
Purdue Pegboard / 3:0-4:5 /half board				
NEPSY – Semantic Verbal Fluency / 3:0-4:5				
NEUROLOGICAL EXAM / 3:0-4:5				
Parenting Stress Index: Parent Form and Ccomputer Printout			L	
Carey Temperament/ [BSQ 3:0-7:11]				
Child Behavior Checklist Parent Form & Computer Printout			L	
MRI SAFETY FORM				
MRI & MR TECHNOLOGIST'S FORM				
COORDINATOR REPORT FORM				
PAYMENT FORMS				

OBJECTIVE – 2

PROCEDURES CHECKLIST: 48 MONTHS

Procedure	Administered/ Sent	Hand Scored or Filled Out	Entered into Web Database/Laptop	Exported and Uploaded to DCC (Laptop Only)
CONTACT SHEET				
CONSENT & ASSENT FORMS				
EXCLUSION CHECKLIST				
FAMILY BIOGRAPHICAL HISTORY FORM				
DEMOGRAPHICS				
HOLLINGSHEAD				
FAMILY INTERVIEW FOR GENETIC STUDIES (FIGS)				
SCAN-TESTING BIOGRAPHICAL FORM				
Preschool Language Scale-3				
Differential Ability Scale: Preschool Form & Computer Printout			W L	
Handedness (eye & foot) / 3:0-4:5				
Purdue Pegboard / 3:0-4:5				
NEPSY – Semantic Verbal Fluency/ 3:0-4:5				
Cambridge Neuropsychological Test Automated Battery				
NEUROLOGICAL EXAM / 3:0-4:5				
Parenting Stress Index: Parent Form and Computer Printout			L	
Carey Temperament [BSQ 3:0-7:11]				
Child Behavior Checklist/ Parent Form & Computer Printout			L	
MRI SAFETY FORM				
MRI & MR TECHNOLOGIST'S FORM				
COORDINATOR REPORT FORM				

PAYMENT FORMS				

OBJECTIVE – 2

IN-HOUSE PROCEDURES (CHILD)

BAYLEY SCALES OF INFANT DEVELOPMENT (BSID)

PRESCHOOL LANGUAGE SCALE-3 (PLS-3)

DIFFERENTIAL ABILITY SCALES (DAS)

HANDEDNESS: 1:0 TO 2:11

HANDEDNESS: 3:0 TO 4:5

PURDUE PEGBOARD (HALF-BOARD)

SEMANTIC VERBAL FLUENCY (NEPSY)

CAMBRIDGE NEUROPSYCHOLOGICAL TEST AUTOMATED BATTERY (CANTAB)

PHYSICAL / NEUROLOGICAL EXAMINATION: 0:0 TO 0:1

PHYSICAL / NEUROLOGICAL EXAMINATION: 0:2 TO 0:11

PHYSICAL / NEUROLOGICAL EXAMINATION: 1:0 TO 2:11

PHYSICAL / NEUROLOGICAL EXAMINATION: 3:0 TO 4:5

BOLD REPRESENTS SCREENING MEASURES!
APPLY EXCLUSION / INCLUSION CRITERIA!

OBJECTIVE – 2

BEHAVIORAL TESTING PROTOCOL AND TIMES

Age	Items Tested	Approx. Length of Testing
3 to 9 months	BSID and PLS-3	1 hour
12, 15 & 18 months	Handedness, BSID and PLS-3	1 hour 30 minutes
24 and 30 months	Handedness, BSID and PLS-3	2 hours
36 months	Handedness, DAS, PLS-3, BSID-PDI, NEPSY, Purdue	2 hours 30 minutes
48 months	Handedness, DAS, PLS-3, CANTAB, NEPSY, Purdue	3 hours

OBJECTIVE – 2

BAYLEY SCALES OF INFANT DEVELOPMENT - II

AGES: 3 months – 36 months

-!!!SCREENING TEST!!!-
Exclusion Criteria:
Mental Development Index, MDI < 70 for Age
Psychomotor Development Index, PDI <70 for Age
Mean=100, SD=15

Bayley, N., 1993. Bayley Scales of Infant Development, 2nd ed. The Psychological Corporation, Harcourt Brace and Company, San Antonio.

GENERAL DESCRIPTION

The BSID-II provides normative data on children ranging in ages from 1-42 months. **For purposes of Objective-2,** the BSID-II, Mental Scale is administered individually to children from 1 month to 2 years, 11 months (0:01 to 2:11). The BSID-II, Motor Scale is administered individually to children from 1 month to 3 years, 6 months (0:01 to 3:6). The BSID-II, Behavioral Rating Scale is administered individually to children from 1 month to 2 years, 11 months (0:01 to 2:11).

1. HAND SCORE TEST
2. ENTER DATA INTO COMPUTER DATABASE
3. COMPUTER SCORE
4. COMPARE HAND SCORING WITH COMPUTER SCORING FOR QUALITY CONFIRMATION

OBJECTIVE – 2

PRESCHOOL LANGUAGE SCALE – 3 (PLS-3)

AGES: 0:3 – 4:5

-!!! SCREENING TEST !!!-
Exclusion Criteria:
Total Language Standard Score <70 for Age
Mean=100, SD=15

Zimmerman, I.L., Steiner, V.G., Pond, R.E., 1992. Preschool Language Scales - 3. The Psychological Corporation, Harcourt Brace Jovanovich, Inc., San Antonio.

GENERAL DESCRIPTION

For purposes of Objective-2, the PLS-3 is individually administered as a speech and language-screening test for children from birth through 4 years, 5 months of age (Birth to 4:5).

1. HAND SCORE TEST
2. ENTER DATA INTO COMPUTER DATABASE
3. COMPUTER SCORE
4. COMPARE HAND SCORING WITH COMPUTER SCORING FOR QUALITY CONFIRMATION

OBJECTIVE – 2

DIFFERENTIAL ABILITY SCALES (DAS)

AGES: 3:0 - 4:5

– !!! SCREENING TEST !!! –
Exclusion Criteria:
General Conceptual Ability (GCA) Score <70 for Age
M=100, SD=15

Elliott, C.D., 1990. Differential Ability Scales. The Psychological Corporation, Harcourt Brace and Company, San Antonio.

GENERAL DESCRIPTION

For purposes of Objective-2, the DAS is administered individually to children at ages 3:0 to 4:5 (Preschool Level), and assesses verbal, reasoning, perceptual and memory abilities. For the Preschool Level of the DAS, children at 3:0 to 3:5 receive the Lower Preschool battery of subtests, while children at 3:6 to 4:5 receive the Upper Preschool battery of subtests.

1. HAND SCORE TEST
2. ENTER DATA INTO COMPUTER DATABASE
3. COMPUTER SCORE
4. COMPARE HAND SCORING WITH COMPUTER SCORING FOR QUALITY CONFIRMATION

OBJECTIVE – 2

HANDEDNESS TEST–1:0 to 2:6

AGES: 1:0 TO 2:6

Almli, C.R. (1999). Measures of hand preference and use appropriate for infants and young children. Washington University in St. Louis, MO.

Almli, C.R., Rivkin, M.J., McKinstry, R.C. (2007). The NIH MRI study of normal brain development (Objective-2): Newborns, infants, toddlers, and preschoolers. *NeuroImage*, 35, 308-325.

GENERAL DESCRIPTION

The Handedness-1:0 to 2:6 Test is used to determine the hand(s) a child uses to reach for and grasp objects.

GENERAL PROCEDURE

Prior to administering the Handedness-1:0 to 2:6 Test, ask the child's parent which hand the child typically uses to grasp and manipulate objects, such as a rattle. On the score sheet, circle the parent response of RIGHT, LEFT, or NO PREFERENCE (i.e., not consistent, frequently uses either hand, etc.).

During the handedness testing, the child sits in a child-sized chair or on the parent's lap while seated at a table. To start the testing, tell the parent that "We want to see which hand your child uses to reach for and grasp objects." Regardless of the position of the child (chair or lap), ask the parent to "lightly hold the child's hands at their sides until the object is placed on the table in front of the child and I say Go." The child's hands need to be at their sides until the object is placed on the table and the tester says, "Go." Until the "Go" command is given, the child's hands cannot be on the table, in the mouth, or in the process of reaching or moving. As necessary, remind the parent to "hold the child's hands at their sides" prior to starting each trial. Also on each trial, remind the parent that you will say "Go" when it is time to release the child's hands so the child can reach for and grasp the object on the table. If the child moves their hand(s) towards the object prior to the object being placed, pick up the object from the table and restart the trial. The tester should feel free to re-start or repeat any trial disrupted by "tester error" or child inattention.

The handedness test is a good "ice breaker" for getting the child comfortable with a longer testing battery, so administering handedness as the first test of a testing session is generally recommended. The entire Handedness Test (i.e., all 8-trials) should be administered in a single testing period. However, if necessary, the test may be administered in two separate testing periods of 4-trials each. The handedness testing should be videotaped and the tape reviewed to ensure accurate scoring of reaching and grasping responses (which can occur very quickly). Camera positioning should be such that the object and the child's midline and hands are clearly visible (e.g., an overhead camera position provides a good image).

The objects used in this handedness assessment are four plastic spools colored red, blue, yellow, or green. Each spool is approximately 4.6 cm (1.8 inches) in diameter at both ends, 3.2 cm (1.2 inches) in diameter at the center, and is 5.7 cm (2.2 inches) in height. On each trial, a spool is set upright on the table surface at the child's midline. The distance of the spool from the child should be within a comfortable arm's reach (i.e., the child should not have to bend over, stretch the upper body, or climb on the table to reach the spool with either hand). It is best to have the spool sitting on its end without support on the table surface when the "Go" command is given. However, if the child bats the spool, tips it over, or knocks it off the table (instead of grasping the spool), the tester should

use their fingers to stabilize the spool sitting on the table surface so that the child cannot displace the spool. A spool should never be handed to the child! As necessary, the tester may tap a spool on the table surface to attract the child's attention and entice the child to reach for the spool. The tester should tap or stabilize spools only if it is necessary to get the child's attention and/or keep the spool sitting upright on the table. Once the child's hands are released, verbal encouragement is allowed and appropriate (e.g., "You can have it." "Take it." "Get the toy.").

A trial starts with the child's hands being lightly held at the child's sides by the parent. The hand(s) used (RIGHT, LEFT, BIMANUAL [both hands]) to reach and/or grasp a spool are circled on the score sheet for each of the 8-trials.

Scoring examples:
a) Circle RIGHT-Reach and RIGHT-Grasp for a right-handed reach and grasp of the spool.
b) Circle BIMANUAL-Reach and BIMANUAL-Grasp only if the reach and grasp movements are bilaterally (right and left) symmetrical and temporally simultaneous for both hands.
c) Circle LEFT-Reach and LEFT-Grasp if the child starts moving the left hand first, then adds the right hand moving (i.e., both hands now moving), but only grasps the spool with the left hand. This would not be an example of a "BIMANUAL-Reach" because the hand movement was not symmetrical and simultaneous.
d) Circle BIMANUAL-Reach and RIGHT-Grasp if the child reaches simultaneously and symmetrically with both hands, but grasps the spool only with the right hand (or grasps the spool first with the right hand). Even if the left hand joins (or replaces) the right hand in the grasp, the grasp is not scored as bimanual because it was not simultaneous (or symmetrical) for both hands.

As indicated in the above examples, the temporal and morphological characteristics of hand use during a reach and grasp are important to recognize and understand, especially for discriminating bimanual/bilateral versus unimanual/unilateral hand-use activities during early development. If the child reaches for and grasps an offered spool with both the right and left hands simultaneously and symmetrically, score BIMANUAL-Reach and BIMANUAL-Grasp on the score sheet. However, if the reach and/or grasp are not strictly simultaneous and symmetrical, then individual hands are scored. For example, both hands are moving simultaneously and symmetrically, but the right-hand touches the spool prior to the left-hand (score as RIGHT-Reach, i.e., the end of the reach was not simultaneous and symmetrical). The child first touched the spool with the right-hand, but then grasped the spool with the left-hand (scored as LEFT-Grasp).

Also, a child may initially touch or grasp a spool with one hand (e.g., right), but then 'pick up' the spool with the other hand or both hands, or the child may grasp and pick up a spool with the right hand and then transfer the spool to the other hand or both hands. For each of those examples, the leading hand (i.e., the first hand to perform the action of grasping) is always scored (i.e., do not score BIMANUAL [which requires simultaneity and symmetry of the two hands] just because the two hands end up on a spool at some point in time). It is also possible for both hands to reach for and touch a spool simultaneously and symmetrically, but then grasp the spool with just the right hand (i.e., scored as BIMANUAL-Reach with RIGHT-Grasp).

Once the child grasps an offered spool, the child is allowed to hold and play with the spool for approximately 5-seconds. Then, the spool is retrieved from the child, and the next spool is presented to the child until a total of 8-trials are completed. Only the spool that is being used for the current trial is visible to the child. The other spools are hidden from the child (e.g., in the tester's lap) until used for a trial.

Notes: If necessary, spools can be constructed from wood and painted in four different colors. It is the size and shape that need to be preserved for the data to be comparable across studies.

OBJECTIVE – 2

HANDEDNESS–1:0 to 2:6

Score Sheet

Hand Child Typically Uses (Parental Report): RIGHT LEFT NO PREFERENCE

CIRCLE HAND FOR REACH AND GRASP

1. Red Spool	Reach **RIGHT** Grasp	Reach **LEFT** Grasp	Reach **BIMANUAL** Grasp
2. Blue Spool	Reach **RIGHT** Grasp	Reach **LEFT** Grasp	Reach **BIMANUAL** Grasp
3. Yellow Spool	Reach **RIGHT** Grasp	Reach **LEFT** Grasp	Reach **BIMANUAL** Grasp
4. Green Spool	Reach **RIGHT** Grasp	Reach **LEFT** Grasp	Reach **BIMANUAL** Grasp
5. Red Spool	Reach **RIGHT** Grasp	Reach **LEFT** Grasp	Reach **BIMANUAL** Grasp
6. Blue Spool	Reach **RIGHT** Grasp	Reach **LEFT** Grasp	Reach **BIMANUAL** Grasp
7. Yellow Spool	Reach **RIGHT** Grasp	Reach **LEFT** Grasp	Reach **BIMANUAL** Grasp
8. Green Spool	Reach **RIGHT** Grasp	Reach **LEFT** Grasp	Reach **BIMANUAL** Grasp

HANDEDNESS–1:0 to 2:6

SCORING

HAND-GRASP SCORING

Number of Grasps (Maximum=8):____ RIGHT ____ LEFT ____ BIMANUAL

Unimanual Laterality Index (ULI):_____ Handedness: RIGHT LEFT MIXED

% Right: _____ % Left: _____ % Bimanual: _____

HAND-REACH SCORING

Number of Reaches (Maximum=8): ____ RIGHT ____ LEFT ____ BIMANUAL

Unimanual Laterality Index (ULI):_____

% Right: _____ % Left: _____ % Bimanual: _____

1. HAND SCORE TEST
2. ENTER DATA INTO COMPUTER DATABASE
3. COMPUTER SCORE
4. COMPARE HAND SCORING WITH COMPUTER SCORING FOR QUALITY CONFIRMATION

SCORING DESCRIPTIONS & PROCEDURES

From this Handedness---1:0 to 2:6 assessment, "hand preference/use" is classified and/or calculated as:

(1) Handedness can be classified as "strongly right-handed" based upon a proportion cut-off or threshold. For example, a classification of "strongly right-handed" is assigned when at least seven of the eight tasks are performed with the right hand. "Not-strongly right-handed" is assigned when six or fewer tasks were completed with the right hand. "Strongly left-handed" can be scored in a similar fashion.

(2) Graded degrees of handedness can be quantified via the calculation of a unilaterality index or percentages (see below).

Unilaterality Index:

Graded scoring of Handedness uses the Unilaterality Index (ULI; Michel et al., 1985). ULI = (number of tasks with a right-hand-active strategy minus [the sum of the number of tasks with a left-hand-active strategy plus the number of tasks with a bimanual-active strategy]) divided by the square root of the (sum of the number of tasks with a right-hand-active strategy plus number of tasks with a left-hand-active strategy plus the number of tasks with a bimanual-active strategy, i.e., a maximum of 8-tasks). The ULI provides a quantitative index of hand use or preference, and can also be used to determine three handedness categories: Right-Handed when the ULI > +1, Left-Handed when the ULI < -1, and Mixed-Handed (i.e., no preference, inconsistent, or ambiguous handedness) when the ULI is between -1 and +1.

Percent Hand Use:

Graded scoring of handedness uses percentage calculations, where the number of uses of one hand (e.g., 5-trials with the right hand) is divided by the total number of trials administered (i.e., 8-trials). Similar proportions can be calculated for left hand use and bilateral hand use.

"Mixed Handed" (i.e., no preference, inconsistent, or ambiguous handedness) is assessed by:

(1) the magnitude of the ULI (e.g., the higher the ULI score is above +1, the more consistent the Right-Handedness, and the closer the ULI score is to zero the greater the degree of Inconsistent-Handedness)

(2) calculation of the percentage of right-active, left-active, and bimanual-active manipulations (e.g., a high percentage of bimanual-active manipulations and/or equal percentages of right-active and left-active manipulations, would indicate a higher degree of Mixed-Handedness).

*ULI : Michel, G.F., Ovrut, M.R., & Harkins, D.A. (1985). Hand-use preference for reaching and object manipulation in 6- through 13-month-old infants. *Genetic, Social and General Psychology Monographs*,111 (4), 409-427.

OBJECTIVE – 2

HANDEDNESS TEST – 3:0 to 4:5

Also Includes: Footedness and Eyedness Subtests

Almli, C.R. (1999). Measures of hand preference and use appropriate for infants and young children. Washington University in St. Louis, MO.

Almli, C.R., Rivkin, M.J., McKinstry, R.C. (2007). The NIH MRI study of normal brain development (Objective-2): Newborns, infants, toddlers, and preschoolers. *NeuroImage*, 35, 308-325.

AGES: 3:0 to 4:5

GENERAL DESCRIPTION

The Handedness Test–3:0 to 4:5 (also used for Objective-1 at 4:6 to 5:11) is used to determine active and passive hand use for manipulation of objects during performance of specific everyday tasks.

GENERAL PROCEDURE

Prior to administering the Handedness Test, the child's parent is asked which hand the child typically uses to manipulate objects (e.g., draw, write, use a spoon), and the response is recorded on the Score Sheet. The parent is also shown the Score Sheet (listing the 10 test tasks) and is asked if there are any tasks that the child does not have any experience performing (e.g., cutting with scissors). If there are tasks that the child has not performed, the tester should demonstrate those tasks to the child (e.g., "Watch me cut with the scissors.") immediately prior to administering that task item. If the child still cannot perform the task, provide a brief written description of their attempted hand use on the score sheet. The child's hand use on these "unable to perform" tasks is described on the Scoring Sheet, but the results are excluded from all graded calculations of handedness performance (see Scoring Section).

Handedness Tests should be videotaped to aid in accurate scoring of hand use via off-line review of the tapes. Camera positioning should provide clear, continuous images of the child's hands, arms, and midline, as well as the task objects that are to be manipulated during performance of the task. Generally, an overhead camera image is best for scoring purposes. During testing, the child should be sitting in a chair with their shoulders "square" to a table, and their "hands in lap" prior to and after performance of the task. Sufficient time to successfully carry out the specific tasks should be provided (see below).

Each of the 10-tasks/trials is started with the instruction to the child to "place their hands in their lap." The object(s) for that specific task is properly positioned on the table surface, and the child is given the "Go" command to perform the task. Never start a task/trial unless the child's hands are stationary in their lap! If the child is moving their hand(s) toward the task items, instruct the child to re-place their hands in the lap and restart the trial. A good strategy is to tell the child to "put their hands in their lap" and that "I will say Go when you can reach for the objects" while you are positioning the task objects on the table surface.

For each of the tasks (trials 1 to 10), it is important that the object(s) are placed on the table surface, in front of the child and centered at the child's midline, and within a distance from the child

that is a comfortable reaching length for the seated child. Our experience with handedness testing indicates that there is a general tendency for tester's to place test objects too far away from the child, and the child has to bend over or even climb on the table to access the objects.

Circle RIGHT, LEFT, or BIMANUAL on the Score Sheet for the active hand(s) used to perform each of the 10-tasks. (Note: The active hand is the hand that produces the action [e.g., turns the lid of a jar], in contrast to the passive hand, which serves to hold and/or stabilize the object [e.g., holds the jar]). For this jar example, note that it is also possible to hold/stabilize the jar by grasping the lid and turning the jar itself to separate the lid from the jar. In both cases, it is the active hand that is scored, i.e., the turning hand is the active hand whether it is turning the lid or the jar. Because developing children can be quite creative, testers need to be aware of these types of possibilities.

If the child performs a task with both the right and left hands being morphologically symmetrical and simultaneously active (e.g., an over-head two-handed throwing of the ball, using both hands to operate the handles of the scissors), score BIMANUAL on the Scoring Sheet for that task. (Note also that it is possible to remove the lid from the jar with both hands being equally active, and scoring of BIMANUAL for hand use, e.g., simultaneous twisting of both the lid and jar—try it.) If the child switches hands during performance of a task (e.g., writing), score the first hand used to perform the task on the Score Sheet and write a note describing the "switch" (i.e., Do NOT score as Bimanual as the hands in this example are not morphologically symmetrical and simultaneously active).

DESCRIPTION OF TASKS / TRIALS AND MATERIALS

HAND USE:

1. Write: Tell the child "hands in your lap." Place a sheet of white paper directly in front of the child and within the child's reach (paper: 21.6 x 27.9 cm [8.5 x 11 in]). Center the pencil (black lead) on the sheet of paper with the tip of the pencil pointing away from the child (child/youth pencil: approximately 0.75-1.0 cm [3/8 inch] diameter, 18 cm [7 in] length). Ask the child to write their name, or make a letter, or make a 'line', as age-appropriate. Start the trial by saying "Go." The hand that holds the pencil is generally the hand actively writing and is scored on the Score Sheet. However, it is possible for one hand to be holding the pencil passively and merely holding the lead to the paper, with the other hand being active by moving the paper under the pencil lead to produce the writing.

2. Draw: Tell the child "hands in your lap." Use the same positioning of paper and pencil as above for Trial-1 (Write). Place four colored lead pencils on the table in front of the child and allow the child to choose one of the colored lead pencils. Then, ask the child to draw a simple object (e.g., person, dog, circle, box, heart), as age-appropriate, with the colored pencil. Start the trial by saying "Go." The active hand is the hand that does the drawing, and this is scored on the Score Sheet. (Materials: paper: 21.6 x 27.9 cm [8.5 x 11 in], pencil: approximately 0.75-1.0 cm [3/8 inch] diameter)

3. Throw: Tell the child "hands in your lap." Place a small, soft, sponge/rubber ball (approximately 18 cm [7 inches] in circumference [e.g. stress/squeeze ball]) on the table surface directly in front of the child and ask the child to throw the ball to you. The active hand is the hand that throws the ball. Scoring requires that the child picks up the ball and throws it. It is not sufficient for the child to use their hand(s) to push or bat the ball. Remember, "hands in lap" and "GO" for each trial.

4. Open Jar: Tell the child "hands in your lap." Place a small, screw-top jar (with lid loosely screwed on jar) directly in front of the child and ask the child to open the jar ("hands in lap" and "GO"). The jar

should be placed with the base on the table surface. The active hand is the hand that does the turning. (Materials: jar: approximately 4.5 cm [1.8 inches] in diameter and 9 cm [4 inches] in height; e.g., spice jar)

5. Use of Hammer: Tell the child "hands in your lap." Place the Peg Holder in front of the child. The hammer is placed at the child's midline between the Peg Holder and the child with the handle of the hammer pointing towards the child. Ask the child to hammer the peg into the hole (hammer, peg and holder are plastic). The active hand is the hand that holds the hammer while pounding. (Materials: toy hammer: 17 cm [6.75 inches] long; peg: 7 cm [2.75 inches] long and 2 cm [0.75 inches] diameter; peg holder: 12 x 23 cm [5 x 9 inches]; e.g. similar to a Turn 'n Tap© toy)

6. Place Person on Tower: Tell the child "hands in your lap. Make and place a 'three block tower with connecting blocks' directly in front of the child. Position a 'person block' between the child and the three block tower. Ask the child to place/stick/connect the 'person' on 'top of the tower.' The active hand is the hand applying the 'person' on the 'tower.' (Materials: 3-block tower: approximately 6 x 3 cm [2.5 x 1.25 inches] and 8 cm [3 inches] height; person block: approximately 7.5 cm [3 inches] height; note: use large, toddler size blocks [similar to Lego-Mega Bloks©] to avoid choking hazard for young children)

7. Complete Puzzle: Tell the child "hands in your lap." Place a puzzle board, with a central piece missing, in front of the child. Position the 'to be placed puzzle piece' between the puzzle board and the child. Ask the child to place the missing piece. The active hand is the hand applying the piece to the puzzle. (Materials: puzzle piece: approximately 6.5 x 8.5 cm [2.5 x 3.25 inches]; self-contained board puzzle: approximately 29.2 x 23.8 cm [11.5 x 9.4 inches])

8. Use Spoon: Tell the child "hands in your lap." Place a spoon (e.g., baby/toddler spoon or small plastic spoon) in front of the child, with spoon handle pointing towards the child. Ask the child to demonstrate how they would use the spoon to eat. The active hand is the hand moving the spoon towards the mouth.

9. Use Scissors: Tell the child "hands in your lap." Place a pair of child's scissors on a piece of paper directly in front of the child, with the cutting tip of the scissors pointing directly away from the child. Ask the child to make a small cut into the piece of paper. The active hand is the hand operating (opening and closing) the scissors. (Materials: scissors: small, non-pointed, hand neutral style [hand neutrality is indicated by the symmetry of the handles of the scissors, i.e., identically-shaped handles]).

10. Ring Rod: Tell the child "hands in your lap." Place a plastic rod stand (such that the rod is vertical, and without any rings)' on the table surface. Place a single, plastic ring between the 'rod stand and the child. Ask the child to put the ring around/over/on the 'rod.' The active hand is the hand applying the ring around the rod. (Materials: rod: 5 cm [2 inches] diameter and 15 cm [6 inches] height; stand: 13 cm [5 inches] diameter)

EYE USE:

Eye Look: Place the telescope standing on one end on the table surface in front of the child. Score the eye the child INITIALLY uses to look through the telescope. Remember, "hands in lap" and "Go" commands. (Materials: small, plastic toy telescope [or half of a toy binocular]: approximately 9.5 cm [3.75 inches] long and 3 cm [1.25 inches] diameter; note that an empty paper towel roll or toilet tissue roll is not recommended as the child may try to use both eyes to look through the large hole)

FOOT USE:

Kick Ball: Have the child stand with both feet together. Place the light, rubber ball on the floor, centered at midline between the child's two feet, and approximately 15.5 x 20.5 cm (6 x 8 inches) in front of the child's feet. Tell child not to move their feet until the "Go" command. A larger, soccer-sized ball is used for the Foot Use task, so do NOT use the smaller "Throw" ball for this task (or vice-versa). Score the foot the child uses to kick the ball. (Materials: ball: approximately 66 cm [26 inches] in circumference) Videotaping should include a clear view of the ball placement and the child's kick.

OBJECTIVE – 2

Handedness Test – 3:0 to 4:5

Also Includes: Footedness and Eyedness Subtests

SCORING SHEET

Hand Child Typically Uses (Parental Report): RIGHT LEFT NO-PREFERENCE

	Score 'Active' Hands		
1. Write your name/ "A"/line:	RIGHT	LEFT	BIMANUAL
2. Draw a line/circle/box/heart:	RIGHT	LEFT	BIMANUAL
3. Throw the Ball to Me:	RIGHT	LEFT	BIMANUAL
4. Open the Jar:	RIGHT	LEFT	BIMANUAL
5. Hammer a Peg into the Hole:	RIGHT	LEFT	BIMANUAL
6. Put the Person on Top of the Tower:	RIGHT	LEFT	BIMANUAL
7. Place the Missing Piece in the Puzzle:	RIGHT	LEFT	BIMANUAL
8. Use the Spoon to Show Me how you Eat	RIGHT	LEFT	BIMANUAL
9. Cut the Paper with the Scissors:	RIGHT	LEFT	BIMANUAL
10. Put the Ring around the Rod:	RIGHT	LEFT	BIMANUAL

Foot & Eye Use Subtests

FOOT USE TEST: Place ball on floor, ask child to "kick the ball" (Score foot used).

RIGHT LEFT

EYE USE TEST: Place telescope on table, ask child to "look at you through it" (Score eye used).

RIGHT LEFT

OBJECTIVE – 2

Handedness Test – 3:0 to 4:5

SCORING: HAND, FOOT & EYE

HANDEDNESS SCORING:

Active Hand (Maximum=10): _____ RIGHT _____ LEFT _____ BIMANUAL

*Bimanual Laterality Index (BLI):_____ Handedness: RIGHT LEFT MIXED

% Right:_____ % Left_____ % Bimanual:_____

FOOTEDNESS SCORING:

1=Right-Foot Kick 2=Left-Foot Kick

EYEDNESS SCORING:

1=Right-Eye Look 2=Left-Eye Look

1. HAND SCORE TEST
2. ENTER DATA INTO COMPUTER DATABASE
3. COMPUTER SCORE
4. COMPARE HAND SCORING WITH COMPUTER SCORING FOR QUALITY CONFIRMATION

DETAILED SCORING DESCRIPTIONS & PROCEDURES

From this Handedness assessment, "hand preference/use" is classified and/or calculated in at least three ways:

(1) Handedness can be classified by the hand used for writing, i.e., right or left.

(2) Handedness can be classified as "strongly right-handed" based upon a proportion cut-off or threshold. For example, a classification of "strongly right-handed" is assigned when at least nine of the 10-tasks is performed with the right hand. "Not-strongly right-handed" is assigned when eight or fewer tasks were completed with the right-hand. "Strongly left-handed" can be scored in a similar fashion.

(3) Graded degrees of handedness can be quantified via the calculation of a bilaterality index or percentages (see below).

Bilaterality Index: Graded scoring of Handedness uses the Bimanual Laterality Index (BLI; Michel et al., 1985). BLI = (number of tasks with a right-hand-active strategy minus [the sum of the number of tasks with a left-hand-active strategy plus the number of tasks with a bimanual-active strategy]) divided by the square root of the (sum of the number of tasks with a right-hand-active strategy plus number of tasks with a left-hand-active strategy plus the number of tasks with a bimanual-active strategy [i.e., a maximum of 10 tasks]). The BLI provides a quantitative index of hand use or preference and can also be used to determine three handedness categories: Right-Handed when the BLI > +1, Left-Handed when the BLI < -1, and Mixed-Handed (i.e., no preference, inconsistent, or ambiguous handedness) when the BLI is between -1 and +1.

Percent Hand Use: Graded scoring of handedness also uses percentage calculations, where the number of uses of one hand (e.g., 5 trials with the right hand) is divided by the total number of trials (i.e., 10 trials). Similar proportions can be calculated for left hand use, and bilateral hand use.

"Mixed Handed" (i.e., no preference, inconsistent, or ambiguous handedness) is assessed in at least two ways:

(1) Magnitude of the BLI: The higher the BLI score is above +1, the more consistent the Right-Handedness. The closer the BLI score is to zero the greater the degree of Inconsistent-Handedness.

(2) Calculation of the percentage of right-active, left-active, and bimanual-active manipulations: A high percentage of bimanual-active manipulations, and/or, equal percentages of right-active and left-active manipulations, would indicate a higher degree of Mixed-Handedness.

*BLI: Michel, G.F., Ovrut, M.R., & Harkins, D.A. (1985). Hand-use preference for reaching and object manipulation in 6- through 13-month-old infants. *Genetic, Social and General Psychology Monographs*,111 (4), 409-427.

OBJECTIVE – 2

PURDUE PEGBOARD (HALF-BOARD)

AGES 3:0 - 4:5

Lafayette Instrument Company, 1985. Purdue Pegboard model #32020 instructions and normative data. Lafayette, IN, Lafayette Instrument.

Gardner, R.A., Browman, M., 1979. The Purdue Pegboard: Normative data on 1,334 school children. J. Clin. Psychol. 1, 156-162.

Wilson, B.C., Iacoviello, J.M., Wilson, J.J., & Risucci, D. (1982). Purdue pegboard performance of normal preschool children. Journal of Clinical Neuropsychology, 4, 19-26.

General:

This test includes three (3) sub-tests: (1) Dominant-hand placement of pegs, (2) Non-Dominant-hand placement of pegs, and (3) Both-hands used simultaneously for placement of pegs. If the child is Right-handed, start testing with the right hand (followed by the Left-hand, then Both-hands). If the child is Left-handed, start testing with the left hand (followed by the Right-hand, then Both-hands). Each of the three sub-tests has a 30-second time limit.

If the child is not clearly Right-handed or Left-handed based on Handedness Testing, use the hand that the child writes (or draws) with as their handedness for this testing.

BE SURE TO HAVE THE CHILD PUT "HANDS IN LAP" AT THE START OF EACH TRIAL

1. HAND SCORE TEST
2. ENTER DATA INTO COMPUTER DATABASE
3. COMPUTER SCORE
4. COMPARE HAND SCORING WITH COMPUTER SCORING FOR QUALITY CONFIRMATION

NEPSY
VERBAL FLUENCY (SEMANTIC ONLY)

AGE: 3:0 TO 4:5

Kemp, S.L., Kirk, U., Korkman, M., 2001. Essentials of NEPSY assessment. John Wiley, New York.
Korkman, M., Krik, U., Kemp, S., 1998. NEPSY: A developmental neuropsychological assessment. The Psychological Corporation, Harcourt Brace and Company, San Antonio.

GENERAL:

This test of verbal fluency is made up of two subtests that measure Semantic and Phonemic fluency (**only the Semantic fluency is utilized for Objective-2**). The child has 60-seconds to produce as many words as possible for each semantic (Animals, Eat or Drink) category.

1. **HAND SCORE TEST**
2. **ENTER DATA INTO COMPUTER DATABASE**
3. **COMPUTER SCORE**
4. **COMPARE HAND SCORING WITH COMPUTER SCORING FOR QUALITY CONFIRMATION**

OBJECTIVE – 2

CAMBRIDGE NEUROPSYCHOLOGICAL TEST AUTOMATED BATTERY (CANTAB)

AGES: 4:0 - 4:5

Cambridge Cognition Limited, 2004. CANTABeclipse version 1.1 [Computer Software]. CeNeS Limited, Cambridge.

CeNeS Limited, 1999. Cambridge Neuropsychological Test Automated Battery (CANTAB) for Windows [Computer Software]. Cambridge Cognition Limited, Cambridge.

Luciana, M., Nelson, C.A., 2002. Assessment of neuropsychological function through use of the Cambridge Neuropsychological Testing Automated Battery: Performance in 4 - to 12 - year old children. Dev. Neuropsychol. 27, 595-624.

General:

The CANTAB assesses a variety of cognitive functions, including learning, memory, attention, and problem solving, as well as tests of executive function and vigilance. **For purposes of the 'MRI Study of Normal Brain Development**,' five subtests are administered in the following fixed order called the 'nihpd battery': (1) Motor Screening, (2) Spatial Span, (3) Spatial Working Memory, (4) Big/Little Circle, and (5) Intra-dimensional/Extra-dimensional Shift.

CANTAB SCORING

Computerized scoring is accomplished utilizing CANTAB's, *Results Manager.*

OBJECTIVE – 2

PHYSICAL / NEUROLOGICAL EXAMINATION

AGES: NEWBORN (0:0)

– !!! SCREENING TEST !!! –
EXCLUSION CRITERIA: SEE LIST ON LAST PAGE

Capute, A.J., Shapiro, B.K., Wachtel, R.C., Gunther, V.A., Palmer, F.B., 1986. The Clinical Linguistic and Auditory Milestone Scale (CLAMS). Identification of cognitive defects in motor-delayed children. Am. J. Dis. Child. 140, 694-698.

Rivkin, M.J., Filipek, P., Neil, J.J., 2003. unpublished neurological assessments.

CHILD EDC AGE:_____YRS_____MOS_____DAYS SEX: MALE FEMALE

Instructions:

1. Read the manual from time to time.
2. Circle one score for each item.
3. Do not skip items even if child is un-testable or refuses: make a note for "un-testable" or "refuses".
4. Describe unusual or specific abnormalities.

Examiner:_____

Materials:

Paper Measuring Tapes for Head Circumference--
NCHS/CDC: Birth to 36 mo Charts for 0:0-0:1
Scale for Body Weight--
NCHS/CDC: Birth to 36 mo Charts for 0:0-0:1
Measuring Device for Body Height (Length)--
NCHS/CDC: Birth to 36 mo Charts for 0:0-0:1
Hand-held Ball Painted Bright Red

A. GENERAL FINDINGS

(001) GENERAL STATE OF HEALTH

Normal	0
Definitely uncomfortable (e.g., bad cold, describe below)	1

(002) GENERAL PHYSICAL

(limited to visual inspection, auscultation of chest for heart and lungs, palpation of abdomen)

Normal	0
Abnormality present but trivial (describe below)	1

Apparent abnormality present (describe below)	2

(003) UNUSUAL FACIAL APPEARANCE

None	0
Present (describe below)	1

(004) MAJOR MALFORMATION

None	0
Present (describe below)	1

(005) Describe all items 001-004 not answered with 0 _____

_____

_____

(006) HEAD CIRCUMFERENCE (Use paper tape; measure largest OFC)

Circumference _____cm **(007)** %ile for age_____

(008) HEIGHT (in centimeters to 00.0cm)

Height _____ cm **(009)** %ile for age_____

(010) WEIGHT

Weight _____ kg **(011)** %ile for age_____

(012) WEIGHT-FOR-LENGTH OR STATURE (HEIGHT)

%ile for age_____

B. MOTOR EXAM

(013-016) HYPERTONIA	**RUE (013)**	**LUE (014)**	**RLE (015)**	**LLE (016)**
None	0	0	0	0
Definite but mild or moderate	1	1	1	1

(017- 020) HYPOTONIA (resistance to passive movement. Ignore mild joint.)

	RUE (017)	**LUE (018)**	**RLE (019)**	**LLE (020)**
None or trivial	0	0	0	0
Mild but definite	1	1	1	1

(021-024) WEAKNESS	**RUE (021)**	**LUE (022)**	**RLE (023)**	**LLE (024)**
None (5/5)	0	0	0	0
Mild (4/5)	1	1	1	1
Moderate (3/5)	2	2	2	2
Severe (1-2/5)	3	3	3	3

(025-026) DEEP TENDON REFLEXES

BICEPS	**RUE (025)**	**LUE (026)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(027-028) TRICEPS	**RUE (027)**	**LUE (028)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(029-030) BRACHIORADIALIS	**RUE (029)**	**LUE (030)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(031-032) QUADRICEPS	**RLE (031)**	**LLE (032)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(033-034) ANKLES	**RLE (033)**	**LLE (034)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(035-036) PLANTAR	**RLE (035)**	**LLE (036)**
Flexor (Toe)	0	0
Extensor (Toe)	1	1
No Toe Movement	2	2

(037-038) TENDON REFLEX ASYMMETRY

None 0
Present 1
(038) Describe _____

_____

(039- 041) ABNORMAL TRUNCAL POSTURE {DYSTONIA}

	R (039)	**L (040)**
None	0	0
Present	1	1

(041) Describe _____

_____

(042-046) CHOREOATHETOSIS OR DYSTONIA OF LIMBS

	RUE (042)	**LUE (043)**	**RLE (044)**	**LLE (045)**
None	0	0	0	0
Present	1	1	1	1

(046) Describe _____

_____

(047-051)) TREMOR

	RUE (047)	**LUE (048)**	**RLE (049)**	**LLE (050)**
None	0	0	0	0
Present	1	1	1	1

(051) Describe (intention, postural, essential etc.) _____

_____

_____

(052-057) TICS

	RUE (052)	LUE (053)	RLE (054)	LLE (055)	HEAD/FACE (056)
None	0	0	0	0	0
Present	1	1	1	1	1

(057) Describe _____

_____

_____

C. CRANIAL NERVES

Ages given in parentheses denote ages by which the majority of children are expected to have achieved the milestone.

(058) VISUAL: FOLLOWS TO MIDLINE (1 month)
(0) Yes _____
(1) No _____

(059) VISUAL: FIXES ON EXAMINER'S FACE (1 month)
(0) Yes _____
(1) No _____

(060-062) OCULAR MOTILITY (CNs III, IV, VI, gaze preference) Test by holding bright red ball in front of subject. Have the infant follow the ball with eyes only. Move ball to elicit cardinal positions of gaze.

	R Eye (060)	L Eye (061)
Normal	0	0
Abnormal	1	1

(062) Describe all abnormalities for items 058 - 061_____

_____

_____

(063- 064) STRABISMUS (A) (None or convergent)
Note: Score Strabismus A or B, not both.

	R Eye (063)	L Eye (064)
None	0	0
Mild esotropia or intermittent esophoria	1	1
Severe esotropia	2	2

(065- 066) STRABISMUS (B)
Note: Score Strabismus A or B, not both.

	R Eye (065)	L Eye (066)
None	0	0
Mild exotropia or intermittent exophoria	1	1
Severe exotropia	2	2

(067- 069) NYSTAGMUS

	R Eye (067)		L Eye (068)
None	0		0
Present but mild	1		1
Circle any seen on lateral gaze:			
Jerk	2	or	2
Pendular	3	or	3
Rotatory	4	or	4

(069) Describe _____

_____

_____

(070-072) FACIAL MOVEMENTS-UPPER MOTOR NEURON (lower facial movement)

	R Side of Face (070)	L Side of Face (071)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(072) Describe _____

_____

_____

(073-075) FACIAL MOVEMENTS-LOWER MOTOR NEURON (upper and lower facial movement)

	R Side of Face (073)	L Side of Face (074)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(075) Describe _____

_____

_____

(076-077) PALATE ELEVATION

	R Palate (076)	L Palate (077)
Symmetric	0	0
Mildly Asymmetric	1	1
Markedly Asymmetric	2	2

(078) JAW MOVEMENTS (Up and Down)

Normal	0
Abnormal	1

(079) TONGUE MOVEMENTS (In and Out)

Protrudes and Retracts easily	0
Abnormal	1

(080) GAG

Normal	0
Abnormal	1

(081) SUCK

Strong	0
Weak	1
None	2

D. COMPLEX TASKS

Ages given in parentheses denote ages by which the majority of children are expected to have achieved the milestone.

(082) RAISES HEAD IN MIDLINE (1 month)
(0) Yes _____
(1) No _____

(083) HAS TIGHT GRASP (1 month)
(0) Yes _____
(1) No _____

(084) LIFTS CHEST OFF TABLE WHEN LYING PRONE (2 months)
(0) Yes _____
(1) No _____

(085) FOLLOWS OBJECT PAST MIDLINE (2 months)
(0) Yes _____
(1) No _____

ENTER ALL SCORES INTO COMPUTER DATABASE

See Exclusion Factors on next page

EXCLUSION FACTORS (NEWBORN)

Circle "YES" for all that apply

1. **Height: <5th %ile** **YES**
2. **Weight: <5th %ile** **YES**
3. **Head Circumference: <5th %ile** **YES**
4. **Weight-for-Length: <5th %ile (‘BIRTH’ STUDIES ONLY)** **YES**
5. **Presence of the following Facial Dysmorphisms:** **YES**
   - **a. repaired or unrepaired palatal cleft** ___
   - **b. repaired or unrepaired labial cleft** ___
   - **c. facial stigmata of Sturge Weber disease** ___
   - **d. facial stigmata of tuberous sclerosis** ___
6. **Mild, moderate, or severe hypertonia** **YES**
7. **Mild, moderate, or severe hypotonia** **YES**
8. **Strength <4/5** **YES**
9. **>10 beats of clonus at ankles** **YES**
10. **Clonus at site other than ankle** **YES**
11. **Dystonia** **YES**
12. **Choreoathetosis** **YES**
13. **Tremor** **YES**
14. **Tics** **YES**
15. **Any clearly noticeable exo- or esotropia** **YES**
16. **Jerk, pendular, rotatory, or monocular nystagmus** **YES**
17. **Asymmetry of facial movement** **YES**
18. **Abnormal Visual Fields** **YES**
19. **Ocular Motility Disturbance** **YES**
20. **Strabismus** **YES**
21. **Markedly Abnormal Facial Movement** **YES**

OBJECTIVE – 2

PHYSICAL / NEUROLOGICAL EXAMINATION

AGES: 3, 6 & 9 MONTHS (0:3-0:9)

– *!!! SCREENING TEST !!!* –
EXCLUSION CRITERIA: SEE LIST ON LAST PAGE

Capute, A.J., Shapiro, B.K., Wachtel, R.C., Gunther, V.A., Palmer, F.B., 1986. The Clinical Linguistic and Auditory Milestone Scale (CLAMS). Identification of cognitive defects in motor-delayed children. Am. J. Dis. Child. 140, 694-698.
Rivkin, M.J., Filipek, P., Neil, J.J., 2003. unpublished neurological assessments.

CHILD EDC AGE:_____YRS_____MOS_____DAYS SEX: MALE FEMALE

Instructions:

1. Read the manual from time to time.
2. Circle one score for each item.
3. Do not skip items, even if child is un-testable or refuses: make a note for "un-testable" or "refuses".
4. Describe unusual or specific abnormalities.

EXAMINER:_____

Materials:

Paper Measuring Tapes for Head Circumference--
NCHS/CDC: Birth to 36 mo Charts for 0:2-0:11
Scale for Body Weight--
NCHS/CDC: Birth to 36 mo Charts for 0:2-0:11
Measuring Device for Body Height (Length)--
NCHS/CDC: Birth to 36 mo Charts for 0:2-0:11
Hand-held Ball Painted Bright Red

A. GENERAL FINDINGS

(001) GENERAL STATE OF HEALTH

Normal	0
Definitely uncomfortable (e.g., bad cold, describe below)	1

(002) GENERAL PHYSICAL

(Limited to visual inspection, auscultation of chest for heart and lungs, palpation of abdomen)

Normal	0
Abnormality present but trivial (describe below)	1

Apparent abnormality present (describe below) 2

(003) UNUSUAL FACIAL APPEARANCE

None	0
Present (describe below)	1

(004) MAJOR MALFORMATION

None	0
Present (describe below)	1

(005) Describe all items 001-004 not answered with 0 _____

_____

_____

(006) HEAD CIRCUMFERENCE (Use paper tape; measure largest OFC)

Circumference _____cm **(007)** %ile for age_____

(008) HEIGHT (in centimeters to 00.0cm)

Height _____ cm **(009)** %ile for age_____

(010) WEIGHT

Weight _____ kg **(011)** %ile for age_____

(012) WEIGHT-FOR-LENGTH OR STATURE (HEIGHT)

%ile for age_____

B. MOTOR EXAM

(013-016) HYPERTONIA	**RUE (013)**	**LUE (014)**	**RLE (015)**	**LLE (016)**
None	0	0	0	0
Mild	1	1	1	1
Moderate	2	2	2	2
Severe	3	3	3	3

(017-020) HYPOTONIA (Resistance to passive movement. Ignore mild joint.)

	RUE (017)	**LUE (018)**	**RLE (019)**	**LLE (020)**
None	0	0	0	0
Mild	1	1	1	1
Moderate	2	2	2	2
Severe	3	3	3	3

(21-24) WEAKNESS	**RUE (021)**	**LUE (022)**	**RLE (023)**	**LLE (024)**
None (5/5)	0	0	0	0
Mild (4/5)	1	1	1	1
Moderate (3/5)	2	2	2	2
Severe (1-2/5)	3	3	3	3

(025-026) DEEP TENDON REFLEXES

BICEPS	**RUE (025)**	**LUE (026)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(027-028) DEEP TENDON REFLEXES

TRICEPS	**RUE (027)**	**LUE (028)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(029-030) DEEP TENDON REFLEXES

BRACHIORADIALIS	**RUE (029)**	**LUE (030)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(031-032) DEEP TENDON REFLEXES

QUADRICEPS	**RLE (031)**	**LLE (032)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(033-34) DEEP TENDON REFLEXES

ANKLES	**RLE (033)**	**LLE (034)**
Normal (+1, +2, +3)	0	0
Clonus	1	1

(035-036) PLANTAR	**RLE (035)**	**LLE (036)**
Flexor (Toe)	0	0
Extensor (Toe)	1	1
No Toe Movement	2	2

(037-038) TENDON REFLEX ASYMMETRY

None 0
Present 1
(038) Describe_____

_____

_____

(039-041) ABNORMAL TRUNCAL POSTURE {DYSTONIA, ATAXIA}

	R (039)	**L (040)**
None	0	0
Present	1	1

(041) Describe _____

_____

_____

(042-046) CHOREOATHETOSIS OR DYSTONIA OF LIMBS

	RUE (042)	LUE (043)	RLE (044)	LLE (045)
None	0	0	0	0
Present	1	1	1	1

(046) Describe _____

(047-051) TREMOR

	RUE (047)	LUE (048)	RLE (049)	LLE (050)
None	0	0	0	0
Present	1	1	1	1

(051) Describe (intention, postural, essential, etc.) _____

(052-057) TICS

	RUE (052)	LUE (053)	RLE (054)	LLE (055)	HEAD/FACE (056)
None	0	0	0	0	0
Present	1	1	1	1	1

(057) Describe _____

C. CRANIAL NERVES

(058-060) OCULAR MOTILITY (CNs III, IV, VI, gaze preference) (Test by holding bright red ball in front of subject. Have the infant follow the ball with eyes only. Move ball to elicit cardinal positions of gaze).

	R Eye (058)	L Eye (059)
Normal	0	0
Abnormal	1	1

(060) Describe _____

(061-062) STRABISMUS

	R Eye (061)	L Eye (062)
None	0	0
Mild esotropia or	1	1
Severe esotropia	2	2
Mild exotropia or exophoria	3	3
Severe exotropia	4	4

(063-065) NYSTAGMUS

	R Eye (063)		L Eye (064)
None	0		0
Present but mild	1		1
Circle any seen on lateral gaze:			
Jerk	2	or	2
Pendular	3	or	3
Rotatory	4	or	4

(065) Describe _____

_____

_____

(066-068) FACIAL MOVEMENTS-UPPER MOTOR NEURON (lower facial movement)

	R Side of Face (066)	L Side of Face (067)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(068) Describe _____

_____

(069-071)) FACIAL MOVEMENTS-LOWER MOTOR NEURON (upper and lower facial movement)

	R Side of Face (069)	L Side of Face (070)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(071) Describe _____

_____

_____

(072-073) PALATE ELEVATION

	R Palate (072)	L Palate (073)
Symmetric	0	0
Mildly Asymmetric	1	1
Markedly Asymmetric	2	2

(074) JAW MOVEMENTS (Up and Down)

Normal	0
Abnormal	1

(075) SUCK

Normal	0
Abnormal	1

(076) TONGUE MOVEMENTS (In and Out)

Protrudes and retracts easily	0
Abnormal	1

(077) GAG

Normal	0
Hyperactive	1
Depressed	2
Absent	3

D. COMPLEX TASKS

Ages given in parentheses denote ages by which the majority of children are expected to have achieved the milestone.

(078-079) TONIC NECK REFLEX PRESENT (2 months) (Performed with child lying in the supine position.)

Head turned to:	**Right Shoulder (078)**	**Left Shoulder (079)**
Present	0	0
Absent	1	1

(080-081) TRUNCAL INCURVATION (Galant's Reflex) ABSENT (2 months) (The examiner holds child securely in the prone position with skin of thorax/abdomen exposed and so that the child's body is able to move freely. The examiner strokes once the paraspinal region from the sacral to cervical region on the left and observes the child's response. After the child reassumes the neutral position, the maneuver is repeated on the right.)

	Left Paraspinal Stimulus (080)	**Right Paraspinal Stimulus (081)**
Absent	0	0
Present	1	1

(082) IN PRONE POSITION, SUPPORTS SELF ON FOREARMS (3 months)

Yes	0
No	1

(083) HOLDS HANDS OPEN AT REST (3 months)

Yes	0
No	1

(084) MOVES ARMS IN UNISON TO GRASP AN OBJECT (3 months)

Yes	0
No	1

(085) MORO REFLEX IS ABSENT (3 months) (The examiner holds infant in the supine position safely and securely in the air so that the arms and legs are free to move. The infant is rapidly lowered while remaining in the examiner's arms in order to elicit the response.)

Yes	0
No	1

(086-087) PALMAR GRASP IS ABSENT (4 months)

	Right Hand (086)	**Left Hand (087)**
Absent	0	0
Present	1	1

(088) ROLLS FRONT TO BACK WHEN PLACED PRONE (5 months)

Yes	0
No	1
Not Done	ND

(089) REACHES FOR CUBE WITH EITHER ARM (5 months) (The cube is presented while the child is held securely in an adult's lap so that both arms are able to move freely.)

Yes	0

No 1

(090-091) TONIC NECK REFLEX ABSENT (6 months)

Head turned to:	**Right Shoulder (090)**	**Left Shoulder (091)**
Present	0	0
Absent	1	1

(092) SITS WELL UNSUPPORTED (6 months)
Yes 0
No 1

(093) CRAWLS (9 months)
Yes 0
No 1

(094) TRANSFERS AN OBJECT FROM ONE HAND TO THE OTHER (9 months)
Yes 0
No 1

(095) USES A PINCER GRASP TO PICK UP A RAISIN (9 months)
Yes 0
No 1

(096) WALKS ALONE (12 months)
Yes 0
No 1

(097) COOS (3 months)
Yes 0
No 1

(098) BABBLES (6 months)
Yes 0
No 1

(099) HAS TWO WORDS OTHER THAN "MAMA" AND "DADA" (12 months)
Note: Parent Report is Acceptable
Yes 0
No 1

ENTER ALL SCORES INTO COMPUTER DATABASE

See Exclusion Factors on next page

EXCLUSION FACTORS (3, 6 & 9 MONTHS)

Circle "YES" for all that apply

1. **Height: <5th %ile** **YES**
2. **Weight: <5th %ile** **YES**
3. **Head circumference: <5nd %ile** **YES**
4. **Presence of the following facial dysmorphisms:** **YES**
   - **a. repaired or unrepaired palatal cleft** ___
   - **b. repaired or unrepaired labial cleft** ___
   - **c. facial stigmata of Sturge Weber disease** ___
   - **d. facial stigmata of tuberous sclerosis** ___
5. **Mild, moderate, or severe hypertonia** **YES**
6. **Mild, moderate, or severe hypotonia** **YES**
7. **Strength <4/5** **YES**
8. **>5 beats of clonus at ankles (for children 2-4 months of age);** **YES**
   any ankle clonus in children > 4 months of age
9. **Clonus at site other than ankle** **YES**
10. **Dystonia** **YES**
11. **Choreoathetosis** **YES**
12. **Tremor** **YES**
13. **Tics** **YES**
14. **Dysmetria** **YES**
15. **Ataxia** **YES**
16. **Any clearly noticeable exo- or esotropia** **YES**
17. **Jerk, pendular, rotatory, or monocular nystagmus** **YES**
18. **Asymmetry of facial movement** **YES**
19. **Abnormal Visual Fields** **YES**
20. **Ocular Motility Disturbance** **YES**
21. **Strabismus** **YES**
22. **Markedly Abnormal Facial Movement** **YES**
23. **Cannot sit independently by 8 months** **YES**
24. **Cannot roll from front to back or back to front by 6 months** **YES**
25. **Tonic neck reflex not absent by 7 months** **YES**

OBJECTIVE– 2

PHYSICAL / NEUROLOGICAL EXAMINATION

AGES: 12, 15, 18, 24 & 30 MONTHS (0:12-0:30)

– !!! SCREENING TEST !!! –
EXCLUSION CRITERIA: SEE LIST ON LAST PAGE

Capute, A.J., Shapiro, B.K., Wachtel, R.C., Gunther, V.A., Palmer, F.B., 1986. The Clinical Linguistic and Auditory Milestone Scale (CLAMS). Identification of cognitive defects in motor-delayed children. Am. J. Dis. Child. 140, 694-698.
Rivkin, M.J., Filipek, P., Neil, J.J., 2003. unpublished neurological assessments.

CHILD EDC AGE:_____YRS_____MOS_____DAYS SEX: MALE FEMALE

Instructions:

1. Read the manual from time to time.
2. Circle one score for each item.
3. Do not skip items, even if child is un-testable or refuses: make a note for "un-testable" or "refuses".
4. Describe unusual or specific abnormalities.

EXAMINER:_____

Materials:

Paper Measuring Tapes for Head Circumference--
NCHS/CDC: Birth to 36 mo Charts for 1:0-2:11
Scale for Body Weight--
NCHS/CDC: Birth to 36 mo Charts for 1:0-2:11
Measuring Device for Body Height (Length)--
NCHS/CDC: Birth to 36 mo Charts for 1:0-2:11
Hand-held Ball Painted Bright Red
Thin Page Book

A. GENERAL FINDINGS

(001) GENERAL STATE OF HEALTH

Normal	0
Definitely uncomfortable (e.g., bad cold, describe below)	1

(002) GENERAL PHYSICAL

(Limited to visual inspection, auscultation of chest for heart and lungs, palpation of abdomen)

Normal	0

Abnormality present but trivial (describe below)	1
Apparent abnormality present (describe below)	2

(003) UNUSUAL FACIAL APPEARANCE

None	0
Present (describe below)	1

(004) MAJOR MALFORMATION

None	0
Present (describe below)	1

(005) Describe all items 001-004 not answered with 0 _____

_____

_____

(006) HEAD CIRCUMFERENCE (Use paper tape; measure largest OFC)

Circumference _____cm **(007)** %ile for age_____

(008) HEIGHT (in centimeters to 00.0cm)

Height _____ cm **009)** %ile for age_____

(010) WEIGHT

Weight _____ kg **(011)** %ile for age_____

(012) WEIGHT-FOR-LENGTH OR STATURE (HEIGHT)

%ile for age_____

B. MOTOR EXAM

(013-016) HYPERTONIA	RUE (013)	LUE (014)	RLE (015)	LLE (016)
None	0	0	0	0
Mild	1	1	1	1
Moderate	2	2	2	2
Severe	3	3	3	3

(017-020) HYPOTONIA (Resistance to passive movement. Ignore mild joint.)

	RUE (017)	LUE (018)	RLE (019)	LLE (020)
None	0	0	0	0
Mild	1	1	1	1
Moderate	2	2	2	2
Severe	3	3	3	3

(021-024) WEAKNESS	RUE (021)	LUE (022)	RLE (023)	LLE (024)
None (5/5)	0	0	0	0

Mild (4/5)	1	1	1	1
Moderate (3/5)	2	2	2	2
Severe (1-2/5)	3	3	3	3

(023-026) DEEP TENDON REFLEXES BICEPS	**RUE (025)**	**LUE (026)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(027-028) DEEP TENDON REFLEXES TRICEPS	**RUE (027)**	**LUE (028)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(029-030) DEEP TENDON REFLEXES BRACHIORADIALIS	**RUE (029)**	**LUE (030)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(031-032) DEEP TENDON REFLEXES QUADRICEPS	**RLE (031)**	**LLE (032)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(033-034) ANKLES	**RLE (033)**	**LLE (034)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(035-036) PLANTAR	**RLE (035)**	**LLE (036)**
Flexor (Toe)	0	0
Extensor (Toe)	1	1
No Toe Movement	2	2

(037-038) TENDON REFLEX ASYMMETRY

None	0
Present	1

(038) Describe_____

_____

_____

(039-041) ABNORMAL TRUNCAL POSTURE {DYSTONIA, ATAXIA}

	R (039)	**L (040)**
None	0	0
Present	1	1

(041) Describe _____

_____

_____

(042-046) CHOREOATHETOSIS OR DYSTONIA OF LIMBS

	RUE (042)	LUE (043)	RLE (044)	LLE (045)
None	0	0	0	0
Present	1	1	1	1

(046) Describe _____

(047-051) TREMOR

	RUE (047)	LUE (048)	RLE (049)	LLE (050)
None	0	0	0	0
Present	1	1	1	1

(051) Describe (intention, postural, essential, etc.) _____

(052-057) TICS

	RUE (052)	LUE (053)	RLE (054)	LLE (055)	HEAD/FACE (056)
None	0	0	0	0	0
Present	1	1	1	1	1

(057) Describe _____

C. CRANIAL NERVES

(058-059) VISUAL FIELDS TO CONFRONTATION

	R Eye (058)	L Eye (059)
Normal	0	0
Abnormal	1	1

(060-062) OCULAR MOTILITY (CNs III, IV, VI, gaze preference) (Test by holding bright red ball in front of subject. Have/Ask the child to follow the ball with eyes only. Move ball to elicit cardinal positions of gaze).

	R Eye (060)	L Eye (061)
Normal	0	0
Abnormal	1	1

(062) Describe abnormalities for items 057-060 _____

(063-064) STRABISMUS

	R Eye (063)	L Eye (064)
None	0	0
Clearly noticeable esotropia	1	1
Clearly noticeable exotropia	2	2

(065- 067) NYSTAGMUS

	R Eye (065)		L Eye (066)
None	0		0
Present but mild in end gaze	1		1
Circle any seen on lateral gaze:	R	or	L
Jerk saccade	2		2
Pendular	3		3
Rotatory	4		4

(067) Describe _____

_____

_____

(068-070) FACIAL MOVEMENTS-UPPER MOTOR NEURON (lower facial movement)

	R Side of Face (068)	L Side of Face (069)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(070) Describe _____

_____

(071-073) FACIAL MOVEMENTS-LOWER MOTOR NEURON (upper and lower facial movement)

	R Side of Face (071)	L Side of Face (072)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(073) Describe _____

_____

_____

(074-075) PALATE ELEVATION

	R Palate (074)	L Palate (075)
Symmetric	0	0
Mildly Asymmetric	1	1
Markedly Asymmetric	2	2

(076) JAW MOVEMENTS (Up and Down)

Normal	0
Abnormal	1

(077) JAW MOVEMENTS (Side to Side)

Normal	0
Abnormal	1

(078) TONGUE MOVEMENTS (In and Out)

Protrudes and retracts easily	0
Abnormal	1

(079) GAG

Normal	0
Hyperactive	1
Depressed	2
Absent	3

D. COMPLEX TASKS

Ages given in parentheses denote ages by which the majority of children are expected to have achieved the milestone.

(080) USES A PINCER GRASP TO PICK UP A RAISIN (9 months)
Yes 0
No 1

(081) WALKS ALONE (12 months)
Yes 0
No 1

(082) RUNS (18 months)
Yes 0
No 1

(083) TURNS PAGES OF A THIN PAGED BOOK 2-3 AT A TIME (18 months)
Yes 0
No 1

(084) TURNS PAGES OF A THIN PAGED BOOK ONE AT A TIME (24 months)
Yes 0
No 1

(085) JUMPS LIFTING BOTH FEET OFF THE FLOOR (30 months)
Yes 0
No 1

(086) HOLDS PENCIL IN AN ADULT FASHION (30 months)
Yes 0
No 1

(087) ALTERNATES FEET GOING UP STEPS (35 months)
Yes 0
No 1

(088) REACHES FOR OBJECTS WITH NO DYSMETRIA (35 months)
Yes 0
No 1

(089) HAS TWO WORDS OTHER THAN "MAMA" AND "DADA" (12 months)
Note: Parental report is Acceptable
Yes 0
No 1

(090) PUTS TWO WORDS TOGETHER WHEN SPEAKING (24 months)
Note: Parental report is Acceptable
Yes 0
No 1

ENTER ALL SCORES INTO COMPUTER DATABASE

See Exclusion Factors on next page

EXCLUSION FACTORS (12, 15, 18, 24 & 30 MONTHS)

Circle "YES" for all that apply

1. **Height: <5th %ile** **YES**
2. **Weight: <5th %ile** **YES**
3. **Head circumference: <5th %ile** **YES**
4. **Presence of the following facial dysmorphisms:** **YES**
    - **a. repaired or unrepaired palatal cleft** ___
    - **b. repaired or unrepaired labial cleft** ___
    - **c. facial stigmata of Sturge Weber disease** ___
    - **d. facial stigmata of tuberous sclerosis** ___
5. **Mild, moderate, or severe hypertonia** **YES**
6. **Mild, moderate, or severe hypotonia** **YES**
7. **Strength <4/5** **YES**
8. **Clonus at any site** **YES**
9. **Dystonia** **YES**
10. **Choreoathetosis** **YES**
11. **Tremor** **YES**
12. **Tics** **YES**
13. **Dysmetria** **YES**
14. **Ataxia** **YES**
15. **Any clearly noticeable exo- or esotropia** **YES**
16. **Jerk, pendular, rotatory, or monocular nystagmus** **YES**
17. **Asymmetry of facial movement** **YES**
18. **Abnormal Visual Fields** **YES**
19. **Ocular Motility Disturbance** **YES**
20. **Strabismus** **YES**
21. **Markedly Abnormal Facial Movement** **YES**
22. **No babbling by 12 months** **YES**
23. **No expressive language (word expression) by 24 months** **YES**

OBJECTIVE – 2

PHYSICAL / NEUROLOGICAL EXAMINATION

AGES: 36 & 48 MONTHS (0:36-0:48)

– *!!! SCREENING TEST !!!* –
EXCLUSION CRITERIA: SEE LIST ON LAST PAGE

Capute, A.J., Shapiro, B.K., Wachtel, R.C., Gunther, V.A., Palmer, F.B., 1986. The Clinical Linguistic and Auditory Milestone Scale (CLAMS). Identification of cognitive defects in motor-delayed children. Am. J. Dis. Child. 140, 694-698.

Rivkin, M.J., Filipek, P., Neil, J.J., 2003. unpublished neurological assessments.

CHILD EDC AGE:_____YRS_____MOS_____DAYS SEX: MALE FEMALE

Instructions:

1. Read the manual from time to time.
2. Circle one score for each item.
3. Do not skip items even if child is un-testable or refuses: in fact, that too is a score (ND-Not Done)
4. Describe unusual or specific abnormalities.
5. Before you start the formal examination, talk to the child. For example, asking about favorite activities or TV shows, will allow you to evaluate conversational ability, language, and social skills.

EXAMINER:_____

Materials:

Paper Measuring Tapes for Head Circumference--
NCHS/CDC: Birth to 36 mo Charts for 3:0
Nellhaus Charts for 3:1-4:5
Scale for Body Weight--
NCHS/CDC: Birth to 36 mo Charts for 3:0
NCHS/CDC 2 to 20yr Charts for 3:1-4:5
Measuring Device for Body Height (Length)--
NCHS/CDC: Birth to 36 mo Charts for 3:0
NCHS/CDC 2 to 20yr Charts for 3:1-4:5
Hand-held Ball Painted Bright Red
Thin Paged Book

A. GENERAL FINDINGS

(001) GENERAL STATE OF HEALTH
Normal 0

Definitely uncomfortable (e.g., bad cold, describe below) 1

(002) GENERAL PHYSICAL

(limited to visual inspection, auscultation of chest for heart and lungs, palpation of abdomen)

Normal 0
Abnormality present but trivial (describe below) 1
Apparent abnormality present (describe below) 2

(003) UNUSUAL FACIAL APPEARANCE

None 0
Present (describe below) 1

(004) MAJOR MALFORMATION

None 0
Present (describe below) 1

(005) Describe all items 001-004 not answered with 0 _____

_____

_____

(006) HEAD CIRCUMFERENCE (Use paper tape; measure largest OFC)

Circumference _____cm **(007)** %ile for age_____

(008) HEIGHT (in centimeters to 00.0cm)

Height _____ cm **(009)** %ile for age_____

(010) WEIGHT

Weight _____ kg **(011)** %ile for age_____

(012) WEIGHT-FOR-LENGTH OR STATURE (HEIGHT)

%ile for age_____

B. MOTOR EXAM

(013-016) HYPERTONIA	RUE (013)	LUE (014)	RLE (015)	LLE (016)
None	0	0	0	0
Mild	1	1	1	1
Moderate	2	2	2	2
Severe	3	3	3	3

(017-020) HYPOTONIA (Resistance to passive movement. Ignore mild joint.)

	RUE (017)	LUE (018)	RLE (019)	LLE (020)
None	0	0	0	0
Mild	1	1	1	1
Moderate	2	2	2	2

Severe	3	3	3	3

(021-024) WEAKNESS	**RUE (021)**	**LUE (022)**	**RLE (023)**	**LLE (024)**
None (5/5)	0	0	0	0
Mild (4/5)	1	1	1	1
Moderate (3/5)	2	2	2	2
Severe (1-2/5)	3	3	3	3

(025-026) DEEP TENDON REFLEXES BICEPS	**RUE (025)**	**LUE (026)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(027-028) DEEP TENDON REFLEXES TRICEPS	**RUE (027)**	**LUE (028)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(029-030) DEEP TENDON REFLEXES BRACHIORADIALIS	**RUE (029)**	**LUE (030)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(031-032) DEEP TENDON REFLEXES QUADRICEPS	**RLE (031)**	**LLE (032)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(033-034) ANKLES	**RLE (033)**	**LLE (034)**
Normal (1+,2+,3+)	0	0
Abnormal	1	1

(035-036) PLANTAR	**RLE (035)**	**LLE (036)**
Flexor (Toe)	0	0
Extensor (Toe)	1	1
No Toe Movement	2	2

(037-038) TENDON REFLEX ASYMMETRY

None	0
Present	1

(038) Describe_____

_____

_____

(039-041) ABNORMAL TRUNCAL POSTURE {DYSTONIA, ATAXIA}	**R (039)**	**L (040)**
None	0	0
Present	1	1

(041) Describe _____

(042-046) CHOREOATHETOSIS OR DYSTONIA OF LIMBS

	RUE (042)	LUE (043)	RLE (044)	LLE (045)
None	0	0	0	0
Present	1	1	1	1

(046) Describe _____

(047-051) TREMOR

	RUE (047)	LUE (048)	RLE (049)	LLE (050)
None	0	0	0	0
Present	1	1	1	1

(051) Describe (intention, postural, essential, etc.) _____

(052-057) TICS

	RUE (052)	LUE (053)	RLE (054)	LLE (055)	HEAD/FACE (056)
None	0	0	0	0	0
Present	1	1	1	1	1

(057) Describe _____

C. CRANIAL NERVES

(058-059) VISUAL FIELDS TO CONFRONTATION (Test each eye individually while covering the contralateral eye.)

	R Eye (058)	L Eye (059)
Normal	0	0
Abnormal	1	1

(060-062) OCULAR MOTILITY (CNs III, IV, VI, gaze preference) (Test by holding bright red ball in front of subject. Ask subject to follow the ball with eyes only. Move ball to elicit cardinal positions of gaze).

	R Eye (060)	L Eye (061)
Normal	0	0
Abnormal	1	1

(062) Describe abnormalities for items 058-061 _____

(063- 064) STRABISMUS

	R Eye (063)	L Eye (064)
None	0	0
Clearly noticeable esotropia	1	1
Clearly noticeable exotropia	2	2

(065-067) NYSTAGMUS

	R Eye (065)		L Eye (066)
None	0		0
Present but mild	1		1
Circle any seen on lateral gaze:			
Jerk	2	or	2
Pendular	3	or	3
Rotatory	4	or	4

(067) Describe _____

_____

_____

(068-070) FACIAL MOVEMENTS-UPPER MOTOR NEURON (lower facial movement)

	R Side of Face (068)	L Side of Face (069)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(070) Describe _____

_____

_____

(071-073) FACIAL MOVEMENTS-LOWER MOTOR NEURON (upper and lower facial movement)

	R Side of Face (071)	L Side of Face (072)
Normal	0	0
Mildly Abnormal	1	1
Markedly Abnormal	2	2

(073) Describe _____

_____

_____

(074-075) PALATE ELEVATION

	R Palate (074)	L Palate (075)
Symmetric	0	0
Mildly Asymmetric	1	1
Markedly Asymmetric	2	2

(076) JAW MOVEMENTS (Up and Down)

Normal	0
Abnormal	1

(077) JAW MOVEMENTS (Side to Side)

Normal	0
Abnormal	1

(078) TONGUE MOVEMENTS (In and Out)

Protrudes and retracts easily	0
Abnormal	1

(079) GAG

Normal	0
Hyperactive	1

Depressed	2
Absent	3

D. COMPLEX TASKS

Ages given in parentheses denote ages by which the majority of children are expected to have achieved the milestone.

(080) TURNS PAGES OF A THIN PAGED BOOK ONE AT A TIME (24 months)
Yes 0
No 1

(081) JUMPS LIFTING BOTH FEET OFF THE FLOOR (30 months)
Yes 0
No 1

(082) HOLDS PENCIL IN AN ADULT FASHION (30 months)
Yes 0
No 1

(083) STANDS MOMENTARILY ON ONE FOOT (36 months)
Yes 0
No 1

(084) HOPS ON ONE FOOT (48 months)
Yes 0
No 1

(085) Maximum number of consecutive hops ____ (code 0-10)

(086) CAN SKIP (48 months)
Yes 0
No 1

(087) CATCHES A BALL WITH BOTH HANDS (48 months)
Yes 0
No 1

(088) CAN SKIP ALTERNATING FEET CONSECUTIVELY (60 months)
Yes 0
No 1

(089) BUTTONS WELL (60 months)
Note: Parental report is Acceptable
Yes 0
No 1

ENTER ALL SCORES INTO COMPUTER DATABASE

See Exclusion Factors on next page

EXCLUSION FACTORS (36 & 48 MONTHS)

Circle "YES" for all that apply

1. **Height <5th %ile** **YES**
2. **Weight <5th %ile** **YES**
3. **Head circumference <5th %ile** **YES**
4. **Presence of the following facial dysmorphisms:** **YES**
   - **a. repaired or unrepaired palatal cleft** ___
   - **b. repaired or unrepaired labial cleft** ___
   - **c. facial stigmata of Sturge Weber disease** ___
   - **d. facial stigmata of tuberous sclerosis** ___
5. **Mild, moderate, or severe hypertonia** **YES**
6. **Mild, moderate, or severe hypotonia** **YES**
7. **Strength <4/5** **YES**
8. **Clonus at any site** **YES**
9. **Dystonia** **YES**
10. **Choreoathetosis** **YES**
11. **Tremor** **YES**
12. **Tics** **YES**
13. **Dysmetria** **YES**
14. **Ataxia** **YES**
15. **Any clearly noticeable exo- or esotropia** **YES**
16. **Jerk, pendular, rotatory, or monocular nystagmus** **YES**
17. **Asymmetry of facial movement** **YES**
18. **Abnormal Visual Fields** **YES**
19. **Ocular Motility Disturbance** **YES**
20. **Strabismus** **YES**
21. **Markedly Abnormal Facial Movement** **YES**

OBJECTIVE – 2

GROWTH CHARTS

HEAD CIRCUMFERENCE GROWTH CHARTS (See Appendix-D)

GROWTH CHARTS: WEIGHT, LENGTH, & WEIGHT-FOR-LENGTH/STATURE (See Appendix-D)

Nellhaus, G., 1968. Head circumference from birth to eighteen years: Practical composite international and interracial graphs. Pediatrics 41, 106-114.

National Center for Health Statistics, 2000. 2000 CDC Growth Charts: United States. Retrieved from http://www.cdc.gov/growthcharts/.

CDC Growth Charts can be downloaded to your PDA (Personal Data Assistant) from the following web site: http://www.statcoder.com/growthcharts.htm#download. This program provides automated growth percentile data (i.e., more accurate than estimating percentiles from paper charts), and its use is recommended for this project (Chen, A.S., 2000. Stat growth charts (Version 2.01) [Computer Software]. StatCoder.com, Austin).

OBJECTIVE – 2

BRAIN SCAN & BEHAVIORAL TESTING FORMS

SCAN-TESTING BIOGRAPHICAL FORM

MRI SAFETY CHECKLIST

MRI SCAN FORM

MR TECHNOLOGIST'S FORM

REPORTING ADVERSE EVENTS

OBJECTIVE – 2

SCAN-TESTING BIOGRAPHICAL FORM

Child Biographical Measures at Time of Behavioral Testing and Brain Scan

AGES: NEWBORN - 48 MONTHS

EDC Date (Expected Date of Confinement) _____/_____/_____ Gender: Male Female

Tester:_____ Scan-Testing Number: 1 2 3

Behavioral Testing

Date _____/_____/_____ Child EDC Age _____yrs_____mos_____days

Brain Scan

Date _____/_____/_____ Child EDC Age _____yrs_____mos_____days

Growth Measures

Date _____/_____/_____ Child EDC Age _____yrs_____mos_____days

Weight _____g _____%

Height (Length) _____cm _____%

Head Circumference _____cm _____%

Weight-for-Height (Length/Stature) _____%

Notes:_____

_____

_____

_____

OBJECTIVE – 2

MRI SAFETY CHECKLIST

This Checklist is applicable to the CHILD undergoing the MRI. However, if a PARENT or PARENTS plan to be with the child in the Scanner Room during the MRI, then these questions are also applicable to that parent (or parents). For all items that apply, circle "YES" and write CHILD and/or PARENT NAME(S), as appropriate, next to the item.

Have you / your child ever been injured by any metallic foreign body (e.g., bullets, BB, shrapnel, etc.)? YES NO
If yes, describe:_____

Have you / your child ever had an injury to the eye involving a metallic object (e.g. metallic slivers, shavings, foreign body, etc.)? YES NO
if yes, describe:_____

Are you pregnant or do you suspect that you are pregnant? YES NO

PLEASE INDICATE IF YOU / YOUR CHILD HAVE ANY OF THE FOLLOWING:

Cardiac Pacemaker	YES	NO
Aneurysm Clip(s)	YES	NO
Implanted Cardiac Defibrillator	YES	NO
Any Type of Biostimulator or Neurostimulator Type:_____	YES	NO
Any Type of Internal Electrode(s)	YES	NO
Pacing Wires	YES	NO
Cochlear Implants	YES	NO
Other:_____	YES	NO
Implanted Insulin Pump	YES	NO
Swan-Ganz Catheter	YES	NO
Halo Vest or Metallic Cervical Fixation Devices	YES	NO
Any Type of Electronic, Mechanical or Magnetic Implant Type:_____	YES	NO
Hearing Aid, Cochlear Implant, Ear Tubes	YES	NO
Any Type of Intravascular Coil, Filter or Stent	YES	NO
Implanted Drug Infusion Device	YES	NO
Any Type of Foreign Body, Shrapnel or Bullet	YES	NO
Heart Valve Prosthesis	YES	NO

Any Type of Ear Implant	YES	NO
Orbital(eye) Prosthesis	YES	NO
Any Type of Implant Held in Place by a Magnet	YES	NO
Any Type of Surgical Clip(s) or Staple(s)	YES	NO
Vascular Access Part	YES	NO
Intraventricular Shunt	YES	NO
Artificial Limb or Joint	YES	NO
Dentures or Braces	YES	NO
Wire Mesh	YES	NO
Implanted Orthopedic Item(s), such as pins, rods, screws, nails, clips, plates, wire, etc) Type:_____	YES	NO
Medication Patches (birth control, tobacco, etc.)	YES	NO
IUD	YES	NO
Pessary	YES	NO
Penile Prosthesis	YES	NO
Diaphragm	YES	NO
Iron Supplements	YES	NO
Tattooed Eyeliner	YES	NO

A small percentage of patients with tattooed eyeliner have experienced transient skin irritation in association with MRI's. You may want to discuss this matter with your physician.

Note that make-up containing metal (e.g., "Glitter"), any type of metal hairpins or hair holders, or analog (dial) watches should NOT be worn in the Scanner Room.

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form and I have had the opportunity to ask questions regarding the information on this form.

_____

Parent(s) / Caregiver(s) Signature Date

_____

Principal Investigator or Designee Signature Date

OBJECTIVE – 2

MRI SCAN FORM

MRI

Date of MRI scan (MM/DD/YYYY): _____ Initials of rater attending scan: _____

Date clinical radiology review complete (MM/DD/YYYY): _____

Did any adverse events occur during the MR scanning session?

No ☐

Yes ☐ **If YES, Report to DCC!**

Did the radiologist report any significant brain abnormalities?

No ☐

Yes ☐ **If YES, Report to DCC!**

Subject Comments: _____

_____

Image Comments: : _____

_____

DTI

Date of DTI scan(MM/DD/YYYY): _____ Initials of rater attending scan: _____

Subject Comments: _____

_____

_____

Image Comments: _____

_____

_____

Objective – 2

MR TECHNOLOGIST'S FORM

This form should be completed by the coordinator and given to the MR technologist prior to each scan.

Important Note to MR Technologist:

In order to ensure confidentiality, all acquired and transferred data should identify subjects **only** by the DCC-ID, PSC-ID, and date of birth.

SUBJECT IDENTIFIERS:

DCC-ID:_____

PSC-ID:_____

Subject's DOB: _____
MM / DD / YYYY

SCAN VISIT:

VISIT *(circle one)*: 1 2 3

✓ *(indicate scans to be acquired)*

- ☐ Objective 2 MRI
- ☐ Ancillary A: MRS
- ☐ Ancillary A: MRSI
- ☐ Ancillary B: DTI

REPORTING ADVERSE EVENTS

Any Adverse Events should be immediately reported to the Site IRB (Human Studies Committee), NIH, DCC, and CCC.

For example: If an Adverse Event occurs related to the MRI, or if there is an adverse finding during a neuroradiology review, IRB/NIH/DCC/CCC should be notified. For MRI scan adverse events, these should also be recorded in the child's MRI Safety Form.

OBJECTIVE – 2

REPORT FORMS AND LETTERS

COORDINATOR'S REPORT FORM

PARENT DAY OF VISIT QUESTIONNAIRE

PARENT LETTER OF RESULTS (BSID-II & PLS-3)

PARENT LETTER OF RESULTS (BSID-II, DAS & PLS-3)

PARENT LETTER OF RESULTS (DAS & PLS-3)

OBJECTIVE – 2

COORDINATOR'S REPORT FORM

DCC# _____ PSC# _____

Date of Scan: _____ Scan Number: _____ EDC: _____

1. Examiner: _____ 2) PSC Site: _____

3) Child's Age Years:Months:Days _____ (Y M D) 4) Successful Scan **Yes** or **No**

5) Length of Behavioral Testing Session*: _____ 6) Length of MRI Session: _____

7) Number of Breaks during Testing: _____ 8) Number of Breaks during MRI: _____

(Please Circle One Response per Item)	Negative		Neutral		Positive
9) Rate the Family's willingness to return for another visit.	1	2	3	4	5
10) What was the child's general reaction to the MRI Scan?	1	2	3	4	5
11) What was the parent's general reaction to the MRI scan? *(If Parent was absent, leave blank)*	1	2	3	4	5
12) What was the child's general reaction to Behavioral Testing?	1	2	3	4	5
13) What was the Parent's general reaction to Behavioral Testing? *(If Parent was absent, leave blank)*	1	2	3	4	5
14) Rate the child's attentiveness during Behavioral Testing.	1	2	3	4	5
15) Rate the parent's general impression of the facilities. *(If Parent was absent, leave blank)*	1	2	3	4	5
16) Rate the parent's general impression of travel/parking. *(If Parent was absent, leave blank)*	1	2	3	4	5

	YES	NO	N/A
17) Did the Parent go in the scanner with the Child?	1	0	9
18) Did a Behavioral Tester or MRI technician go in the scan room with child?	1	0	9

19) Specific Comments from Parent and/or Child about the Test or Scan and/or Examiner Comments (record comments on back of page).

*OPTIONAL: Breakdown of Behavioral Testing Session time (indicate time duration for each task)

BX testing _____

Neuro Exam _____

Travel _____

FIGS _____ Total Time _____ (Record Total Time in item 5)

PARENT DAY OF VISIT QUESTIONNAIRE – OBJECTIVE-2

PSC#:_____ **DCC #:**_____

Date of Scan:_____ **EDC:**_____ **Scan Number:**_____

	Poor		Fair		Excellent
1. How did your child react to the Behavioral Testing? (Circle one)	**1**	**2**	**3**	**4**	**5**
2. How did your child react to the MRI Scan? (Circle one)	**1**	**2**	**3**	**4**	**5**
3. How did you react to the Behavioral Testing? (Circle one)	**1**	**2**	**3**	**4**	**5**
4. How did you react to the MRI Scan? (Circle one)	**1**	**2**	**3**	**4**	**5**
5. Did you go into the Scan with your child?	**Yes**				**No**
6. What was your general impression of the Behavioral Testing staff? (Circle one)	**1**	**2**	**3**	**4**	**5**
7. What was your general impression of the MRI Scan staff? (Circle one)	**1**	**2**	**3**	**4**	**5**

8. Parent's comments or suggestions about Test and Scan Visits:

9. Parent's comments about Test and Scan facilities or travel to the facilities:

10. Parent's comments/suggestions about study communications between visits:

11. What was your main motivation for participating in this study?

OBJECTIVE – 2

PARENT LETTER OF RESULTS (BSID-II & PLS-3)

To the Parents of _____:

Thank you very much for bringing _____in for research testing! Your child was _____ months / years old at the time and received the Bayley Scales of Infant Development-II (BSID-II) and the Preschool Language Scale-3 (PLS-3). The BSID-II assesses your child's mental and motor development. The PLS-3 assesses your child's auditory comprehension and expressive language skills. Test results are presented below:

Your child's score in the area of mental development (includes learning, language, and personal-social skills) on the BSID-II was:
_____ in the advanced range.
_____ in the developing normally range.
_____ in the delayed range.

Your child's score in the area of motor development (includes fine and gross motor skills) on the BSID-II was:
_____ in the advanced range.
_____ in the developing normally range.
_____ in the delayed range.

Your child's score in the area of auditory comprehension on the PLS-3 was:
_____ in the advanced range.
_____ in the developing normal range.
_____ in the delayed range.

Your child's score in the area of expressive communication on the PLS-3 was:
_____ in the advanced range.
_____ in the developing normal range.
_____ in the delayed range.

Your child's total language score on the PLS-3 was:
_____ in the advanced range.
_____ in the developing normal range.
_____ in the delayed range.

The above findings cannot be used to predict future achievement in school. The BSID-II assesses only current levels of mental and motor development. It provides information on whether or not your child has achieved certain mental and motor milestones at different developmental stages.

All testing is conducted for research purposes only. We hope that our research will ultimately help children that are having developmental problems, and you are helping us do that! If you have any questions about the above results, please call _____.

Sincerely,

OBJECTIVE – 2

PARENT LETTER OF RESULTS (BSID-II, DAS & PLS-3)

To the Parents of: _____

Thank you for bringing _____ in for research testing! Your child was _____ years old at that time and received the *Differential Ability Scales (DAS),* the *Bayley Scales of Infant Development-II (BSID-II) Motor Scale,* and the *Preschool Language Scale-3.* Test results are briefly described below.

Differential Ability Scale

Your child's verbal score including such tasks as vocabulary and comprehension were:
_____ advanced.
_____ within the normal range.
_____ below average, and may benefit from more in-depth evaluation from special services.

Your child's nonverbal score including such tasks as pattern construction and copying were:
_____ advanced.
_____ within the normal range.
_____ below average, and may benefit from more in-depth evaluation from special services.

Your child's General Conceptual Ability (GCA) score, which is an overall measurement of abilities important to learning including verbal, perceptual, reasoning and memory skills was: _____

Preschool Language Scale

Your child's auditory comprehension score was:
_____ advanced.
_____ within the normal range.
_____ below average, and may benefit from more in-depth evaluation from special services.

Your child's expressive language score was:
_____ advanced.
_____ within the normal range.
_____ below average, and may benefit from more in-depth evaluation from special services.

Your child's total communication score was:
_____ advanced.
_____ within the normal range.
_____ below average, and may benefit from more in-depth evaluation from special services.

Bayley Scales of Infant Development–II

Your child's score in the area of motor development (includes fine and gross motor skills) on the BSID-II was:
_____ in the advanced range.
_____ in the developing normally range.
_____ in the delayed range.

Your child was also given a variety of other learning and memory tests designed to measure ***how*** children learn and remember things. These tests are still being developed, thus these results are not available at this time. All testing is conducted for research purposes ***only***. We hope that our research will ultimately help children learn better, and you are helping us do that! If you have any questions about the above results, please call _____.

Sincerely,

Site Coordinator

OBJECTIVE – 2

PARENT LETTER OF RESULTS (DAS & PLS-3)

To the Parents of: _____

Thank you very much for bringing _____ in for research testing! Your child was _____ years old at that time and received the *Differential Ability Scales* and the *Preschool Language Scales.* Test results are presented below.

Differential Ability Scales

Your child's verbal score (including such tasks as vocabulary and comprehension) was:
_____ advanced.
_____ within the normal range.
_____ below average (may benefit from more in-depth evaluation).

Your child's nonverbal score (including such tasks as pattern construction and copying) was:
_____ advanced.
_____ within the normal range.
_____ below average (may benefit from more in-depth evaluation).

Your child's General Conceptual Ability (GCA) score, which is an overall measurement of verbal, perceptual, reasoning, and memory skills, was:
_____ advanced.
_____ within the normal range.
_____ below average (may benefit from more in-depth evaluation).

Preschool Language Scales

Your child's auditory comprehension score was:
_____ advanced.
_____ within the normal range.
_____ below average (may benefit from more in-depth evaluation).

Your child's expressive language score was:
_____ advanced.
_____ within the normal range.
_____ below average (may benefit from more in-depth evaluation).

Your child's total communication score was:
_____ advanced.
_____ within the normal range.
_____ below average (may benefit from more in-depth evaluation).

All testing of your child was conducted for research purposes only. We hope that our research will ultimately help children that are having developmental problems, and you are helping us do that! If you have any questions about the above results, please call _____.

Sincerely,

Site Coordinator

OBJECTIVE - 2

MISCELLANEOUS

WEBSITE

USING THE DATABASE

EXCLUSIONS DURING DEVELOPMENT AND THE DATABASE

VISITS (TIMEPOINTS)

CONFERENCE CALLS AND WEEKLY REPORTS

OBJECTIVE – 2

WEBSITE

To access information about the project, and to apply for acess to the project's data, interested parties should go to (www.NIH-PediatricMRI.org).

OBJECTIVE – 2

USING THE DATABASE

This section should be read and implemented in conjunction with the section on Visits and Exclusions prior to utilizing the database.

The Project Database is maintained by the Data Coordinating Center at the Montreal Neurological Institute. All users of the database should be familiar with the *Laptop and Database User Guide* which is available from the project website (http://www.bic.mni.mcgill.ca/nihpd/). The database is divided, roughly, into two parts: The MRI database and a Behavioral database. The MRI database contains all data related to acquired scans (both successful and unsuccessful scans submitted to the database). This database is available on the project website under the MRI Browser link.

The Behavioral database is located on the project website under the NIHPD Study Database Login. Data is either entered into the web database (web entry), entered into the laptop, or administered on the laptop and uploaded to the web database. Below is a table outlining how data entry is completed for each instrument.

Test	Web Entry	Laptop Scoring	Web Upload
BSID BRS	√		
BSID MDI	√		
BSID PDI	√		
CANTAB			√
Carey	√		
CBCL		√	√
DAS	√	√	√
Family Biographical History Form	√		
Family Interview for Genetic Studies	√		
Handedness	√		
NEPSY	√		
Neurological Exam	√		
Parenting Stress Index		√	√
PLS-3	√		
Purdue	√		
Scan Testing Biographical Form	√		
Screening and Exclusion Form	√		

Occasionally, errors will occur while utilizing the database. These errors include both data entry errors and database architectural errors. When errors occur in the database, they should be reported to the DCC via Mantis. The link to Mantis is sometimes referred to as “Report a Bug.” Mantis allows both database users and the database architects to report, monitor, and repair issues relating to the database.

OBJECTIVE – 2

EXCLUSIONS DURING DEVELOPMENT AND THE DATABASE

This section should be read and implemented in conjunction with the section on Visits and the Database prior to utilizing the database.

If a child is excluded prior to successfully completing their first visit (i.e., if they fail one of the points on the Screening and Exclusion form or if they fail the neurological exam) they should receive appropriate payment for whatever part of the study they have finished and should be excluded from the study (i.e. no additional follow-up will be done with this family).

However, from time to time, exclusions will develop as the child develops. When this occurs, the child should be followed-up for their remaining visits necessary to complete a total of three visits (i.e., if the child has a successful visit 1 and is excluded at visit 2, the site should bring the child in and acquire visit 3 if possible).

Indicating Exclusions in the web database
The DCC has divided data entry into three sections: (1) Instruments Administered Prior/During the Hospital Visit; (2) Instruments Administered to Candidate During the Medical Center Visit; (3) Instruments Administered to the Parent During the Medical Center Visit. The instruments used in (1) are the Screening and Exclusion Form, FIGS, and as appropriate, CBCL. All other instruments are either in (2) or (3). The database is designed such that data should be entered into section one and a "Pass/Fail" decision must be made about the "Screening Stage" prior to starting the "Visit Stage" which contains sections two and three.

For Objective-2, all exclusions are found on the Screening and Exclusion form. Therefore, all exclusions should be marked on the Screening and Exclusion form in the database. Because of this, the Screening Stage should **automatically** be marked as "Failure" when a child matches an exclusionary item. Additionally, if the exclusion occurs on the BSID, DAS, PLS-3 or the Neuro exam, the Visit stage should be marked as "Failure."

Coding Failures (i.e., Exclusions) in the Web Database
The web database classifies instruments (e.g., CBCL, BSID, Screening and Exclusion Form) in two Stages: The Screening Stage and the Visit Stage. Each visit to the Medical Center must be coded "Pass", "Failure", or "Withdrawn" in these two stages in the web database.

Screening Stage Exclusionary Instruments:
CBCL
FIGS
Screening and Exclusion Form

Visit Stage Exclusionary Instruments:
DAS
BSID
PLS-3
Neuro Exam (Growth Measures & Neurological Problems)

If a child is excluded from Objective-2 for an exclusionary item from the CBCL, FIGS, Screening and Exclusion Form, DAS, BSID, PLS-3, Neuro Exam, then the Screening Stage should be marked as Failure.

If a child is excluded from Objective-2 for an instrument that is listed under the Visit stage (i.e., BSID, DAS, PLS-3, Neuro Exam) then the Visit Stage AND the Screening Stage should both be marked as Failure.

If the child is excluded for any of the Growth Measures obtained at the child's visit to the site (e.g., Body Weight, Head Circumference), then mark the child as excluded at both the Screening Stage and the Visit Stage.

OBJECTIVE – 2

VISITS (TIMEPOINT)

This section should be read and implemented in conjunction with the section on Exclusions and the Database prior to utilizing the database.

A successful Objective-2 visit is one where the child completes the entire age testing battery, the physical/neurological exam, **and** the site is able to acquire a successful scan data set, as defined by the DCC. These events constitute a successful visit. This is the only way to achieve a successful visit; however, there are a number of ways in which a visit can be incomplete. Some examples of incomplete visits include:

- Behavioral testing completed, but the scan is not;
- Behavioral testing is completed, a scan is acquired, but the scan does not pass the DCC quality confirmation process;
- A scan is acquired, but behavioral testing is not;
- Scan/behavioral testing do not fall in age windows.

All data associated with a particular timepoint must match (i.e., all laptop, web, scan and paper data must have the same label).

- Data associated with a scan submitted to the DCC should be labeled with a **V** followed by the number of scan (e.g., 1=1st successful behavioral testing/scan set; 2=2nd successful behavioral testing/scan, etc).
- If there is data associated with a scan not submitted to the DCC, this data should be labeled as **"i"** followed by a letter which indicates the number of occurrences (e.g., a=1st behavioral data without a scan, b=2nd set of behavioral data without a scan, etc).
- If a scan is acquired and there is no behavioral data, the visit should be labeled **V** and the appropriate number as described above. However, the site will need to note that the visit is not complete.
- If a scan is acquired and later fails the DCC Quality Confirmation process, the visit label should **not** be changed, as a scan has been submitted to the DCC and all other data needs to match this scan.

The table below demonstrates different conditions and how visit labeling should be applied to each condition.

Age	6 mos	9 mos	12 mos	15 mos	18 mos	24 mos	30 mos
Submitted Scan Data	No	Yes	No	Yes	No	Yes	Yes
Behavior Testing	Yes	No	Yes	Yes	Yes	Yes	Yes
Visit Grouping Label	"ia"	"v1"*	"ib"	"v2"**	"ic"	"v3"	"v4"*

*Because there is no behavioral data acquired at V1, it is necessary to bring the child in for V4 to meet the minimum project requirements of 3 visits with a completed scan and completed behavioral data.

** Although the child was first seen by the PSC at 6 mos, the child's cohort would be 15 mos, since this is the first time that a scan and behavioral data are **both** acquired.

OBJECTIVE – 2

CONFERENCE CALLS AND WEEKLY REPORTS

There is generally a bi-weekly Objective–2 conference call. On these calls, relevant project topics are discussed. These topics may include:

- Information about current publications
- Changes to the database
- Changes to the sampling plan
- Procedural changes
- Staffing changes

Minutes from these conference calls are archived on the project website (http://www.bic.mni.mcgill.ca/nihpd/). In addition to the bi-weekly Objective–2 conference call there are also minutes for the Steering Committee Call, Behavioral Investigators call, and the Objective-1 PSC call.

Prior to the call, an agenda for the conference call and the most current Objective–2 Progress Report are emailed to the sites, NIH and DCC. The Progress Report summarizes the current recruitment status for Objective–2 and indicates which areas are still open for recruitment.

OBJECTIVE – 2

APPENDICES

APPENDIX-A: DRUGS AND MEDICATIONS

A-1 COMMON MATERNAL MEDICATIONS DURING PREGNANCY AND BREASTFEEDING

A-2 MATERNAL DRUG SCHEDULES

APPENDIX-B: TRACKING LOG GUIDE

APPENDIX-C: QUALITY CONTROL FOR BEHAVIORAL MEASURES

APPENDIX-D: GROWTH CHARTS

OBJECTIVE-2

APPENDIX-A-1 COMMON MATERNAL MEDICATIONS DURING PREGNANCY AND BREASTFEEDING

AGES: 0:0 – 4:5

-!!!SCREENING!!!-
Exclusion Criteria:
Medications with "Yes" under FETAL RISK and/or BREASTFEEDING RISK are Exclusionary

Breastfeeding Category Key

X	*Contraindicated*
x	*Contraindicated by the Manufacturer*
OK	*Compatible*
WC	*With Caution*
ND	*No Data*

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
ACE Inhibitors	Captopril	Antihypertensive	D, C	Yes		OK
ACE Inhibitors	Enalapril	Antihypertensive	D, C	Yes		OK
ACE Inhibitors	Lisinopril	Antihypertensive	D, C	Yes		OK
Acetaminophen		Analgesic	B			OK
Acetazolamide	Diamox	Diuretic	C			OK
Acyclovir	Zovirax	Antiviral	C			OK
Adenosine	Adenocard	Antiarrhythmic	C			ND
Albuterol	Proventil	Antiasthmatic	C			OK
Alendronate	Fosamax	Bone Metabolism	C			ND
Alfentanil		Opiate Agonist	C			OK
Allopurinol		Gout, Uricosuric	C			OK
Alprazolam	Xanax	Antianxiety	D	Yes	Yes	X
Amantadine	Symmetrel	Antiviral	C		Yes	X
Amikacin	Amikin	Antibiotic	C			OK
Amiloride	Midamor	Potas.SparingDiur.	B	Yes		ND

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Aminocaproic acid	Amicar	Hemostatic	C			ND
Aminoglycosides		Antibiotic	C			OK
Aminopterin			X	Yes		ND
Aminopyhlline	Aminop	Antiasthmatic	C			OK
Amiodarone	Cordarone	Antiarrhythmic	C		Yes	X
Amitroptyline	Elavil	Antidepressant	D	Yes		OK
Amlodipine	Norvasc	Antihypertensive	C			ND
Amoxapine	Asendin	Antidepressant	C			ND
Amoxicillin	Amoxil	Antibiotic	B			OK
Amoxicillin	Trimox	Antibiotic	B			OK
Amoxicillin/Clavulante	Augmentin	Antibiotic, Penicillin	B			OK
Amphetamine		Resp&CerebralStim.	C		Yes	X
Amphotericin B	Amphocin	Antifungal	B			ND
Ampicillin		Antibiotic	B			OK
Aspirin		Nonster.Antiinflam.	D, C	Yes	Yes	WC
Atenolol	Tenormin	Antihypertensive	D, C	Yes		OK
Atorvastatin	Lipitor	Antilipemic	X	Yes		ND
Atropine		Antimuscarinic	C			OK
Azathioprine	Imuran	Antineoplastic	D	Yes		ND
Azithromycin	Zithromax	Anti-infective	B			OK
Aztreonam	Azactam	Antibiotic	B			OK
Baclofen		SkeletalMuscleRelax.	C			OK
Barbituates			D	Yes	Yes	WC
Beclomethasone	Vancencase	Corticosteroid	C			ND
Beclomethasone	Vanceril	Corticosteroid	C			ND
Benazepril	Lotensin	Antihypertensive	D, C	Yes		OK
Benztropine	Cogentin	Anti-ParkisonianAgent	C			ND
Betamethasone	Celestone	Corticosteroid	C			ND
Betaxolol	Betoptic	Tx. of Glaucoma	C		Yes	WC

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Bethanechol		Cholinergic	C		Yes	X
Bismuth subsalicylate	Pepto Bismol	Antidiarrheal Agent	C		Yes	WC
Bleomycin		Antineoplastic	D	Yes		ND
Bromocriptine	Ergoset	Tx. Hyperprolactinemia	C		Yes	X
Bromocriptine	Parlodel	Tx. hyperprolactinemia	C		Yes	X
Brompheniramine		Antihistamine	C			OK
Bumetanide	Bumex	Diuretic	D	Yes	Yes	X
Bupropion	Wellbutrin	Antidepressant	B		Yes	WC
Bupropion	Zyban	Antidepressant	B		Yes	WC
Buspirone	Buspar	AnxiolyticSedatHypno.	B		Yes	WC
Butalbital		Inter.Act.barbituate	C			ND
Butoconazole	Femstat	Antifungal, Topical	C			ND
Butoconazole	Mycelex	Antifungal, Topical	C			ND
Butorphanol	Stadol	Analgesic	C			OK
Caffeine	Stimulant		B		Yes	WC
Calcitonin	Miacalcin	Calcium metabolism	C			ND
Calcium Channnel			C			OK
Captopril		Antihypertensive	D	Yes		OK
Carbamazepine	Carbatrol	Anticonvulsant	C			OK
Carbamazepine	Tegretal	Anticonvulsant	C			OK
Carbimazole		Antithyroid Agent	D	Yes	Yes	WC
Carisoprodol	Soma	SkeletalMuscleRelax.	C		Yes	X
Cefprozil	Cefzil	AntibiotCephalosporin	B			OK
Cefuroxime	Ceftin	AntibiotCephalosporin	B			OK
Celecoxib	Celbrex	Nonsteroid.Antiinflam.	C			ND
Cephalexin	Keflex	AntibiotCephalosporin	B			OK
Cephalexin	Kefteb	AntibiotCephalosporin	B			OK
Cephalosporins			B			OK
Cetirzine	Zyrtec	Antihistamine	B		Yes	x

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Chloramphenicol	Chloromycetin	Antibiotic	C		Yes	X
Chlordiazepoxide	Librium	Sedative	D	Yes	Yes	X
Chloropropamide		Antidiabetic	D	Yes	Yes	WC
Chloroquine	Aralen	Antimalarial Agent	C			OK
Chlorothiazide	Diuril	Diuretic	D	Yes		OK
Chlorpheniramine	Efidac	Antihistamine	B			OK
Chlorpheniramine	Teldrin	Antihistamine	B			OK
Chlorpromazine	Thorazine	Tranquilizer	C		Yes	WC
Chlorpropamide	Diabinese	Antidiabetic Agent	C		Yes	X
Cholestyramin	Prevalite	Antilipemic Agent	C			ND
Cimetidine	Tagamet	Tx. Of peptic ulcer	B			OK
Ciprofloxacin	Cipro	Antiinfective	C		Yes	X
Cisapride	Propulsid	Gastroesophag.Reflux	C			OK
Cisplatin		Antineoplastic	D	Yes	Yes	WC
Citalopram	Celexa	SSRI	C		Yes	X
Clarithromycin	Biaxin	Antiinfective	C			ND
Clavulante	Augmentin	Antibiotic, Penicillin	B			OK
Clemastine		Antihistamine	C		Yes	WC
Clindamycin	Cleocin	Antibiotic	B			OK
Clofibrate	Atromid-S	Antilipemic Agent	C		Yes	X
Clomiphene	Clomid	Nonsteroid.Ovul.Stim	X	Yes		ND
Clomiphene	Serophine	Nonsteroid.Ovul.Stim	X	Yes		ND
Clonazepam	Klonopin	Anticonvulsant	D	Yes	Yes	X
Clonidine	Catapres	Antihypertensive	C		Yes	X
Clopidogrel	Plavix	Oral Antithrombic	B			ND
Clotrimazole	Lotrimin	Topical Antifungal	B			ND
Clotrimazole	Mycelex	Topical Antifungal	B			ND
Cloxaxillin	Cloxapen	Antibiotic	B			OK
Cocaine			X, C	Yes	Yes	X

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Codeine		Opiate Agonist	C			OK
Colchicine		Treatment of gout	D	Yes	Yes	X
Contraceptive, oral			X	Yes		OK
Cromolyn Sodium		Antiasthmatic	B			ND
Crotamiton		Tx. of scabies	C			ND
Crotamiton		Tx. of scabies	C			OK
Cyclobenzaprine	Flexeril	SkeletalMuscleRelax.	B			ND
Cyclophosphamide	Cytoxan	Antineoplastic Agent	D	Yes	Yes	X
Cyclosporine	Neoral	Antineoplastic Agent	C		Yes	X
Cyclosporine	Sandimmune	Antineoplastic Agent	C		Yes	X
Cyproheptadine	Periactin	Antihistamine	B			OK
Desipramine			C			OK
Desmopressin			B			ND
Dexamethasone			C			ND
Dexfenfluramine			C		Yes	X
Dextroamphetamine			D	Yes	Yes	X
Diazepam			D	Yes	Yes	WC
Diazoxide			C		Yes	X
Dicumarol			D	Yes		OK
Dienestrol			X	Yes		ND
Diethylstilbesterol			X	Yes		ND
Digoxin	Lanoxin	Antiarrhythmic	C			OK
Dihydrostreptomycin			X	Yes		ND
Diltiazem	Cardizem	CalciumChannelBlock.	C			OK
Diphenhydramine		Antihistamine	C			ND
Diphenhydramine	Benadryl	Antihistamine	B			OK
Dipyridamole			C			OK
Disopyramide			C			OK
Disulfiram			X	Yes		ND

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Divalproex	Depakote	Anticonvulsant	D	Yes		OK
Donepezil	Aricept	Acetylcholinester.Inhib	C			ND
Doxazosin	Cardura	AlphaAdrenergicRec.Inhib.	C			ND
Doxepin			C		Yes	X
Doxorubicin			D	Yes	Yes	X
Doxycycline			D	Yes		OK
Doxylamine		Antihistamine	B			ND
Droperidol			C			ND
Enalapril	Vasotec	Antihypertensive	D, C	Yes		OK
Ephedrine			C			OK
Epoetin Alfa			C			ND
Ergotamine			X	Yes	Yes	X
Erthromycin Estolate			X	Yes	Yes	WC
Erythromycin			B			OK
Estrogens			X	Yes		ND
Ethambutol			B			OK
Ethanol			X	Yes	Yes	X
Ethosuximide			C			OK
Etretinate			X	Yes		ND
Famotidine			B			OK
Felodipine	Plendil	CalciumChannelBlock.	C			ND
Fexoenadine	Allegra	Antihistamine	C			ND
Fluconazole			C		Yes	X
Fluoxetine	Prozac	Antidepressant	B			ND
Fluphenazine			C			ND
Fluticasone	Flovent	Corticosteroid	C			ND
Fluvastatin	Lescol	Hyperlipidemia	X	Yes		ND
Fosinopril		Antihypertensive	D, C	Yes	Yes	x
Furosemide	Lasix	Diuretic	C		Yes	WC

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Gabapentin	Neurontin	Anticonvulsant	C			ND
Gallium-69			X	Yes	Yes	X
Gaseous Anesthetics			X	Yes		ND
Gemfibrozil	Lopid	Hyperlipidemia	C			ND
Gentamicin	Garamycin	Antibiotic	C			OK
Glimepiride	Amaryl	Blood Glucose Reg.	C			ND
Glipizide	Glucotrol	Blood Glucose Reg.	C		Yes	X
Glyburide	Diabeta	Blood Glucose Reg.	C		Yes	X
Glyburide	Micronase	Blood Glucose Reg.	C		Yes	X
Gold salts			C		Yes	WC
Guaifenesine	Robitussin	Expectorant	C			ND
Guanethidine	Ismelin	AntihypertensiveAgent	B			OK
Hydralazine		Antihypertensive	C			OK
Hydrochlorothiazide		Diuretic Antihypertens.	D	Yes		ND
Hydrocodone	Vicodin	Narcotic Analgesic	D, B	Yes		ND
Hydromorphine	Dilaudid	Narcotic Analgesic	D, B	Yes		OK
Hydroxyzine	Atarax	Anxiolytic-Sedative,Hypnot.	C			ND
Hydroxyzine	Vistaril	Anxiolytic-Sedative,Hypnot.	C			ND
Hydrozychloroquine	Plaquenil	Antimalarial Agent	C			OK
Ibuprofin	Advil	Nonster. Antiinflam.	B			OK
Ibuprofin	Motrin	Nonster. Antiinflam.	B			OK
Imipramine	Tofranil	Antidepressant	D	Yes	Yes	WC
Imiquimod			B			ND
Indomethacin	Indocin	Nonster. Antiinflam.	D, B	Yes		OK
Insulin			B			OK
Iodine-125			X	Yes	Yes	X
Iodine-131			X	Yes		ND
Ipratropium	Atrovent	Antimuscarinic	B			ND
Irbesartan	Avapro	Antihypertensive	D, C	Yes		ND

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Isoniazid		Antituberculosis	C		Yes	WC
Isoproterenol		Sypathomimetic	C			OK
Isosorbide	Imdur	Vasodilating agent	B			ND
Isotretinoin	Accutane	Skin&MucousMemb.	X	Yes	Yes	X
Kanamycin			D	Yes		OK
Ketorolac	Toradol	Nonsteroid.Antiinflam	C		Yes	X
Labetolol		Antihypertensive	C			OK
Lansoprazole	Prevacid	Control of stomach acid	B			ND
Latanoprost	Opthalmic Solution	Tx. of Glaucoma	C			ND
Latanoprost	Xalatan	Tx. of Glaucoma	C			ND
Leukotriene Receptor	Montelukast	Antiasthmatic	B			ND
Leukotriene Receptor	Zafirlukast	Antiasthmatic	B			ND
Levodopa			C		Yes	X
Levofloxacin	Levaquin	Antiinfective	C			ND
Levothyroxine	Levoxyl	Thyroid Agent	A			OK
Levothyroxine	Syntheroid	Thyroid Agent	A			OK
Lidocaine			B			OK
Lindane			B		Yes	X
Lisinopril	Prinivil	Antihypertensive	D, C	Yes		ND
Lisinopril	Zestril	Antihypertensive	D, C	Yes		ND
Lithium			D	Yes	Yes	X
Loperamide			B			OK
Loracarbef	Lorabid	Antibiotic	B			ND
Loratadine	Claritin	Antihistamine	B			OK
Lorazepam			D	Yes	Yes	WC
Losartan	Cozaar	Antihypertensive	D, C	Yes		ND
Magnesium			B			OK
Mebendazole			C	Yes		ND

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Meclizine			B			ND
Medroxyprogesteron			D	Yes		OK
Mefenamic Acid	Ponstel	Nonsteroid.Antiinflam.	C			OK
Meperidine			D, B	Yes	Yes	X
Mepindolol			C			OK
Meprobamate			D	Yes	Yes	X
Mercaptopurine		Immunosuppressant	D	Yes		ND
Mesalamine			B		Yes	WC
Metformin	Glucophage	Blood Glucose Reg.	B		Yes	X
Methadone		Narcotic	D, B	Yes	Yes	WC
Methadone		Narcotic	B		Yes	WC
Methimazole			D	Yes	Yes	WC
Methotrexate		Immunosuppressant	D	Yes		ND
Methotrexate	Methotrex	Antineoplastic Agent	D	Yes	Yes	X
Methotrexate	Rheumatrex	Antineoplastic Agent	D	Yes	Yes	X
Methyldopa		Antihypertensive	B			OK
Methyldopa			C			OK
Methylphenidate	Concerta	Respir.CerebralStim.	C			ND
Methylphenidate	Ritalin	Respir.CerebralStim.	C			ND
Methyltestoste			X	Yes		ND
Metoclopramide	Reglan	Tx.emesis,reflux,gastroparesis	B			ND
Metoprolol			C			OK
Metronidazole	Flagyl	Antiinfec.Antiprotoz.Antibact.	B		Yes	X
Metronidazole	Protostat	Antiinfec.Antiprotoz.Antibact.	B		Yes	X
Miconazole			B			OK
Mineral Oil			C		Yes	WC
Minoxidil		Antihypertensive	C			OK
Misoprostol			X	Yes	Yes	X
Mometasone	Elocon	Antiinflam.Topical	C			ND

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Mometasone	Nasonex	Antiinflam.Topical	C			ND
Morphine		Narcotic	D, B	Yes		OK
Nabumetone	Relafen	Nonsteroid.Antiinflam	C		Yes	x
Nalidixic Acid	NegGram	Antiinfective	C			OK
Naproxen	Anaprox	Nonster. Antiinflam.	B			OK
Naproxen	Naprosyn	Nonster. Antiinflam.	B			OK
Nefazodone	Serzone	Antidepressant	C			ND
Nicotine			X	Yes	Yes	X
Nifedipine	Adalat	Antihypertensive	C			OK
Nifedipine	Procardia	Antihypertensive	C			OK
Nitrofurantoin	Furandantin	Urinary antiinfective	B			OK
Nitrofurantoin	Macrodantin	Urinary antiinfective	B			OK
Nitrogylcerine	Nitrol	Vasodilating Agt.	C			ND
Nitrogylcerine	Nitrolingual	Vasodilating Agt.	C			ND
Nizatidine	Axid	H2-ReceptorAntag.	B			OK
Nortriptyline			D	Yes		ND
NSAID			D, C, B	Yes		OK
Nystatin			B			OK
Odansetron			B			ND
Ofloxacin	Floxin	Antiinfective	C		Yes	X
Olanzapine	Zyprexa		C		Yes	x
Olsalazine			C		Yes	WC
Omeprazole	Prilosec	Control of stomach acid	C		Yes	X
Oxacillin		Antibiotic	B			OK
Oxaprozin	Daypro	Nonsteroid Antiinflam	C			ND
Oxazepam			C		Yes	WC
Oxycodone		Narcotic	B			OK
Paromycin			C			OK
Paroxetine	Paxil	Antidepressant	B		Yes	X

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Penicillamine			D	Yes	Yes	X
Penicillin			B			OK
Pentazocine		Narcotic	B			ND
Permethrin		ScabicideTopic.	B			ND
Phenobarbital			D	Yes	Yes	WC
Phenothiazine			C		Yes	WC
Phenylpropanolamine		Decongestant	C			OK
Phenytoin		Anticonvulsant	D	Yes		OK
Pindolol			B			OK
Piroxicam		Nonsteroid Antiinflam	C			OK
Podofilox		Tx. of Genital warts	C			ND
Podophyllin		Tx. of Genital warts	C			ND
Potassium Chloride	K-Dur		C			OK
Potassium Iodide			D	Yes	Yes	X
Prednisone			B			OK
Premarin			X	Yes	Yes	X
Primidone			D	Yes	Yes	WC
Procainamide			C			OK
Prochloperazine			C			OK
Progesterone			D	Yes		OK
Progestins			X	Yes		ND
Promethazine			C		Yes	WC
Propanolol			C			OK
Propoxyphene			C			OK
Propylthiouracil			D	Yes	Yes	WC
Pseudoephedrine			C			OK
Pyrantel Pamoate			C			ND
Pyridostigmine			C			OK
Pyridoxine			A			OK

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Pyrimethamine			C			OK
Quinapril	Accupril	Antihypertensive	D, C	Yes		ND
Quinidine			C			OK
Quinine			X	Yes		ND
Raloxifene	Evista	Sel.EstrogenRecept.Modul.	X	Yes	Yes	X
Ramipril	Altace	Antihypertensive	D, C	Yes	Yes	x
Ranitidine		Antihistamine	B			OK
Repaglinade		Antidiabetic	C		Yes	X
Reserpine		Antihypertensive	C			OK
Rifampin		Antituberculosis Agt.	C			OK
Risperidone	Risperdal	Antipsychotic	C			ND
Rofecoxib	Vioxx	Nonsteroid Antiinflam.	C			ND
Salmeterol	Serevent	Bronchodilator	C			ND
Secobarbital			D	Yes		OK
Setraline	Zoloft	Antidepressant	B			ND
Simvastatin	Zocor	Antipemic Agent	X	Yes		ND
Spironolactone			C			OK
Steroids		Antiinflammatory	X	Yes	Yes	X
Sulbactam			B			OK
Sulfamethaxazole			C			OK
Sulfapyridine			C		Yes	X
Sulfasalazine			D, B	Yes	Yes	WC
Sulfisoxazole			C		Yes	X
Sumatriptan			C			OK
Technitium-99m			X	Yes	Yes	X
Temazepam			C			OK
Terbinafine	Lamisil	Antifungal	B		Yes	X
Terbutaline			B			OK
Terfenadine			C			ND

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Tetracyclines			D	Yes		OK
Thalidomide			X	Yes		ND
Theophylline			C			OK
Thioridazine			C			OK
Thyroid Hormone			A			OK
Ticarcillin			B			OK
Timolol			C			OK
Tinidazole			C		Yes	X
Tobramycin			D	Yes		OK
Tolbutamide			C	No		OK
Tolmetin			C			OK
Tramadol			C		Yes	X
Triamcinolone Acentoni	Azmacort	Corticosteroid	C			ND
Triamterene	Diazide	Antihypertensive	C		Yes	X
Trifluoperazine			C			OK
Trimethadione			X	Yes		ND
Trimethobenzamide			C			OK
Trimethoprim			C			OK
Triprolidine			C			OK
Troglitazone	Rezulin	Antidiabetic Agent	B		Yes	X
Vaccine, Cholera			C			OK
Vaccine, Haemophilus			C			OK
Vaccine, Hepatitis A			C			OK
Vaccine, Hepatits B			C			OK
Vaccine, Influenza			C			OK
Vaccine, Measles			X	Yes		ND
Vaccine, Meningococcus			C			ND
Vaccine, Mumps			X	Yes	Yes	ND

Generic Name	Brand Name	Drug Type	Schedule	Fetal Risk	Breastfeeding Risk	Breastfeeding Category
Vaccine, Plague			C			ND
Vaccine, Pneumococcus			C			OK
Vaccine, Poliovirus Inactive			C			ND
Vaccine, Poliovirus Live			C			ND
Vaccine, Rabies			C			ND
Vaccine, Rubella		Meruvax	C		Yes	WC
Vaccine, TC-83		VenezuelanEquineEncephalitis	X	Yes		ND
Vaccine, Typhoid			C			ND
Vaccine,Yellow Fever			D	Yes		ND
Valproic Acid			D	Yes		OK
Vancomycin			C			ND
Venlafazine	Effexor	Antidepressant	C		Yes	X
Verapamil			C			OK
Vitamin A			X, A	Yes		OK
Vitamin B12			C			OK
Vitamin D			D, A	Yes		OK
Warfarin	Coumadine	Anticoagulant	D	Yes		OK
Zidovudine			C		Yes	X
Zolpidem			B			OK

APPENDIX-A-2 MATERNAL DRUG SCHEDULES

Category A: Controlled human studies have demonstrated no fetal risk.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Levothyroxine	Levoxyl Synthroid	Thyroid Agent	Compatible	
Pyridoxine			Compatible	
Thyroid hormone			Compatible	
Vitamin A			Compatible	X in high doses
Vitamin D			Compatible	Also classified D

Category B: Animal studies indicate no fetal risk and no well-controlled human studies have been conducted, or animal studies demonstrated an adverse effect that was not confirmed in controlled human studies.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Acetaminophen		Analgesic	Compatible	
Amiloride	Midamor	Potassium Sparing Diuretic	No data	First trimester exposure resulted in two fold increase in major birth defects, however sample size was 28
Amoxicillin	Amoxil Trimox	Antibiotic	Compatible	
Amoxicillin/ Clavulante	Augmentin	Antibiotic, Penicillin	Compatible	
Amphotericin B	Amphocin	Antifungal	No data	
Ampicillin		Antibiotic	Compatible	
Azithromycin	Zithromax	Anti-infective	Compatible	
Aztreonam	Azactam	Antibiotic	Compatible	No human data; no teratogenic effects in animal studies
Bupropion	Wellbutrin Zyban	Antidepressant	With caution	
Buspirone	Buspar	Anxiolytic, Sedative, Hypnotic	With caution, may be of concern	
Caffeine		Stimulant	Compatible when not used in excess	
Cefprozil	Cefzil	Antibiotic, Cephalosporin	Compatible	
Cefuroxime	Ceftin	Antibiotic, Cephalosporin	Compatible	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Cephalexin	Keflex, Keftab	Antibiotic, Cephalosporin	Compatible	
Cephalosporins			Compatible	
Cetirizine	Zyrtec	Antihistamine	Not compatible according to drug manufacturer	
Chlorpheniramine	Efidac Teldrin	Antihistamine	Compatible	
Cimetidine	Tagamet	Treatment of Peptic Ulcer	Compatible	
Clindamycin	Cleocin	Antibiotic	Compatible	
Clopidogrel	Plavix	Oral Antithrombic Agent	Compatibility unknown	
Clotrimazole	Lotrimin, Mycelex	Topical Antifungal	No data	
Cloxaxillin	Cloxapen	Antibiotic	Compatible	
Cromolyn Sodium		Antiasthmatic	No data	
Cyclobenzaprine	Flexeril	Skeletal Muscle Relaxant	Compatibility unknown	
Cyproheptadine	Periactin	Antihistamine	Compatible	
Desmopressin			No data	
Diphenhydramine	Benadryl	Antihistamine	Compatible	
Doxylamine		Antihistamine	No data	
Erythromycin			Compatible	
Ethambutol			Compatible	
Famotidine			Compatible	
Fluoxetine	Prozac	Antidepressant	No data	
Guanethidine	Ismelin	Antihypertensive Agent	Compatible	
Hydrocodone	Vicodin	Narcotic Analgesic	No data	Also classified D
Hydromorphone	Dilaudid	Narcotic Analgesic	Compatible	Also classified D
Ibuprofin	Advil, Motrin	Nonsteroidal Antiinflammatory Agent	Compatible	May inhibit labor if used near term
Imiquimod			No data	
Indomethacin	Indocin	Nonsteroidal Antiinflammatory Agent	Compatible	Also classified D, may inhibit labor if used near term
Insulin			Compatible	
Ipratropium	Atrovent	Antimuscarinic	Compatibility unknown	No adequate human studies

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Isosorbide Mononitrate	Imdur	Vasodilating Agent	Compatibility unknown	
Lansoprazole	Prevacid	Control of Stomach Acid	Compatibility unknown	
Lidocaine			Compatible	
Lindane			Alternate feeding method required for four days after exposure	
Loperamide			Compatible	
Loracarbef	Lorabid	Antibiotic	No data	
Loratadine	Claritin	Antihistamine	Compatible at standard dose	
Leukotriene Receptor Antagonists	Zafirlukast, Montelukast	Antiasthmatic	No data	
Magnesium			Compatible	
Meclizine			No data	
Meperidine		Narcotic	Minimal dose	Also classified D
Mesalamine			With caution	
Metformin	Glucophage	Blood Glucose Regulator	Contraindicated	
Methadone		Narcotic	With caution	Also classified D
Methyldopa		Antihypertensive	Compatible	
Metoclopramide	Reglan	Treatment of emesis, gastric reflux, and gastroparesis	No data, increases milk production	
Metronidazole	Flagyl, Protostat	Antiinfective Agent, Antiprotozoal, and Antibacterial	Contraindicated, discontinue feeding 24 hours after last dose	
Miconazole			Compatible	
Morphine		Narcotic	Compatible, inhibits milk ejection	Also classified D
Naproxen	Naprosyn, Anaprox	Nonsteroidal Antiinflammatory	Compatible	May inhibit labor if used near term
Nitrofurantoin	Furadantin, Macrodantin	Urinary Antiinfective	Compatible	
Nizatidine	Axid	H2-Receptor Antagonist	Compatible	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
NSAID			Compatible	May be classified B or C in early pregnancy, D near term
Nystatin			Compatible	
Odansetron			No data	
Oxacillin		Antibiotic	Compatible	
Oxycodone		Narcotic	Compatible	
Paroxetine	Paxil	Antidepressant	Possible long-term neurobehavioral effects of concern	
Penicillin			Compatible	
Pentazocine		Narcotic	No data	
Permethrin	Scabicide, topical		No data	
Pindolol			Compatible	
Prednisone			Compatible	
Ranitidine		Antihistamine	Compatible	
Sertraline	Zoloft	Antidepressant	No data	
Sulbactam			Compatible	
Sulfasalazine			With caution	Classified B in early pregnancy, D near term
Terbinafine	Lamisil	Antifungal	Contraindicated	
Terbutaline			Compatible	
Ticarcillin			Compatible	
Troglitazone	Rezulin	Antidiabetic Agent	No data, contraindicated	
Zolpidem			Compatible	No human data

Category C: Animal studies demonstrate adverse effects on the fetus and no controlled human studies have been conducted, or studies in humans and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
ACE Inhibitors	Enalapril, Captopril, Lisinopril	Antihypertensive	Compatible	Classified C first trimester, D second and third trimesters
Acetazolamide	Diamox	Diuretic	Compatible	
Acyclovir	Zovirax	Antiviral	Compatible	
Adenosine	Adenocard	Antiarrhythmic	No data	No adequate human studies
Albuterol	Proventil	Antiasthmatic	Compatible	
Alfentanil		Opiate Agonist	Compatible	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Alendronate	Fosamax	Bone Metabolism	No data	No adequate human studies
Allopurinol		Gout,Uricosuric	Compatible	No adequate human studies
Amantadine	Symmetrel	Antiviral	Contraindicated	
Amikacin	Amikin	Antibiotic	Compatible	No adequate human studies
Aminocaproic acid	Amicar	Hemostatic	No data	No adequate human studies
Aminoglycosides		Antibiotic	Compatible	
Aminopyhlline	Aminop	Antiasthmatic	Compatible	
Amiodarone	Cordarone	Antiarrhythmic	Contraindicated	No adequate human studies
Amlodipine	Norvasc	Antihypertensive	No data	No adequate human studies
Amoxapine	Asendin	Antidepressant	Compatibility unknown	
Amphetamine		Respiratory and Cerebral Stimulant	Contraindicated	Nonteratogenic when used under medical supervision
Aspirin		Nonsteroidal Antiinflammatory Agent	With caution	Classified C in low dose (<150 mg/day), D in standard doses
Atenolol		Antihypertensive	Compatible	
Atropine		Antimuscarinic	Compatible	
Baclofen		Skeletal Muscle Relaxant	Compatible	
Beclomethasone	Vancenase, Vanceril	Corticosteroid	No data	
Benzepril	Lotensin	Antihypertensive Agent	Compatible	Classified C first trimester, D second and third trimesters
Benztropine	Cogentin	Anti-Parkinsonian Agent	No data	Possible association with cardiovascular defects
Betamethasone	Celestone	Corticosteroid	No data	
Betaxolol	Betoptic	Treatment of Glaucoma	With caution	
Bethanechol		Cholinergic Agent	Contraindicated	
Bismuth subsalicylate	Pepto Bismol	Antidiarrheal Agent	With caution	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Bromocriptine	Parlodel, Ergoset	Treatment of Hyper-prolactinemia	Contraindicated	
Brompheniramine		Antihistamine	Compatible	
Butalbital		Intermediate-Acting Barbituate	No data	
Butoconazole	Femstat, Mycelex	Antifungal, Topical	No data	
Butorphanol	Stadol	Analgesic	Compatible	
Calcitonin	Miacalcin	Calcium Metabolism	No data	
Calcium Channel Blockers			Compatible	
Carbamazepine	Tegretal, Carbatrol	Anticonvulsant	Compatible	
Carisoprodol	Soma	Skeletal Muscle Relaxant	Avoid breastfeeding	
Celecoxib	Celebrex	Nonsteroidal Antiinflammatory Agent	Compatibility unknown	
Chloramphenicol	Chloromycetin	Antibiotic	Contraindicated	
Chloroquine	Aralen	Antimalarial Agent	Compatible	
Chlorpromazine	Thorazine	Tranquilizer	With caution	
Chlorpropamide	Diabinese	Antidiabetic Agent	Contraindicated	
Cholestyramine	Prevalite	Antilipemic Agent	No data	
Ciprofloxacin	Cipro	Antiinfective	Contraindicated, discontinue feeding for 48 hours after last dose	
Cisapride	Propulsid	Treatment of Gastroesophageal Reflux Disease	Compatible	
Citalopram	Celexa	SSRI	Avoid breastfeeding	No adequate human studies
Clarithromycin	Biaxin	Antiinfective	No data	
Clemastine		Antihistamine	With caution	
Clofibrate	Atromid-S	Anilipemic Agent	Contraindicated	
Clonidine	Catapres	Antihypertensive	Contraindicated	
Cocaine			Contraindicated	Classified X as an illicit drug

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Codeine	Opiate Agonist		Compatible	
Crotamiton		Treatment of Scabies	No data	
Cyclosporine	Neoral, Sandimmune	Antineoplastic Agent	Contraindicated	
Desipramine			Compatible	
Dexamethasone			No data	
Dexfenfluramine			Not recommended	
Diazoxide			Contraindicated	
Digoxin	Lanoxin	Antiarrhythmic	Compatible	
Diltiazem	Cardizem	Calcium channel blocker	Compatible	
Diphenhydramine		Antihistamine	No data	
Dipyridamole			Compatible	
Disopyramide			Compatible	
Docusate Salts			With caution	
Donepezil	Aricept	Acetyl-cholinesterase inhibitor	Compatibility unknown	
Doxazosin	Cardura	Alpha adrenergic receptor inhibitor	Compatibility unknown	
Doxepin			Contraindicated	
Droperidol			No data	
Enalapril	Vasotec	Antihypertensive	Compatible	Classified C first trimester, D second and third trimesters
Ephedrine			Compatible	
Epoetin Alfa			No data	
Ethosuximide			Compatible	
Felodipine	Plendil	Calcium channel blocker	Compatibility unknown	
Fexofenadine	Allegra	Antihistamine	Compatibility unknown	
Fluconazole			Contraindicated	
Fluphenazine			No data	
Fluticasone	Flovent	Corticosteroid	Compatibility unknown	No adequate human studies
Fosinopril		Antihypertensive	Not compatible according to drug manufacturer	Classified C first trimester, D second and third trimesters
Furosemide	Lasix	Diuretic	With caution	
Gabapentin	Neurontin	Anticonvulsant	Compatibility unknown	No adequate human studies

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Gemfibrozil	Lopid	Hyperlipidemia	No data	
Gentamicin	Garamycin	Antibiotic	Compatible	
Glimepiride	Amaryl	Blood Glucose Regulator	No data	
Glipizide	Glucotrol	Blood Glucose Regulator	Contraindicated	
Glyburide	Diabeta,Micronase	Blood Glucose Regulator	Contraindicated	
Gold salts			With caution	
Guaifenesine	Robitussin	Expectorant	No data	
Hydralazine		Antihypertensive	Compatible	
Hydroxyzine	Atarax,Vistaril	Anxiolytic-Sedative and Hypnotic	No data	
Hydro-zychloroquine	Plaquenil	Antimalarial Agent	Compatible	
Irbesartan	Avapro	Antihypertensive	No data	Classified C first trimester, D second and third trimesters
Isoniazid		Antituberculosis Agent	Compatible if also on pyridoxine	
Isoproterenol		Sypathomimetic Agent	Compatible	
Ketorolac	Toradol	Nonsteroidal Antiinflammatory Agent	Contraindicated	
Labetolol		Antihypertensive	Compatible	
Latanoprost	Xalatan Opthalmic Solution	Treatment of Glaucoma	Compatibility unknown	
Levodopa			Contraindicated	
Levofloxacin	Levaquin	Antiinfective	Compatibility unknown	
Lisinopril	Prinivil, Zestril	Antihypertensive	No data	Classified C first trimester, D second and third trimesters
Losartan	Cozaar	Antihypertensive	No data	Classified C first trimester, D second and third trimesters
Mebendazole			Compatibility unknown	Manufacturer recommends against use in pregnancy
Mefenamic Acid	Ponstel	Nonsteroidal Antiinflammatory	Compatible	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Mepindolol			Compatible	
Methyldopa			Compatible	
Methylphenidate	Concerta, Ritalin	Respiratory and Cerebral Stimulant	No data	
Metoprolol			Compatible	
Mineral Oil			With caution	
Minoxidil		Antihypertensive Agent	Compatible	
Mometasone	Elocon, Nasonex	Antiinflammatory Agent, Topical	No data	
Nabumetone	Relafen	Nonsteroidal Antiinflammatory Agent	Not recommended according to drug manufacturer	
Nalidixic Acid	NegGram	Antiinfective	Compatible	
Nefazodone	Serzone	Antidepressant	No data	
Nifedipine	Adalat, Procardia	Antihypertensive Agent	Compatible	
Nitrogylcerine	Nitrolingual,Nitrol	Vasodilating Agent	No data	
NSAID			Compatible	Classified B or C in early pregnancy, D near term
Ofloxacin	Floxin	Antiinfective	Contraindicated	
Olanzapine	Zyprexa		Not recommended according to drug manufacturer	
Olsalazine			With caution	
Omeprazole	Prisolec	Control of stomach acid	Not recommended	
Oxaprozin	Daypro	Nonsteroidal Antiinflammatory	No data	
Oxazepam			Minimal dose	
Paromycin			Compatible	
Phenothiazine			With caution	
Phenyl-propanolamine		Decongestant	Compatible	
Piroxicam		Nonsteroidal Antiinflammatory	Compatible	
Podofilox		Treatment of Genital Warts	No data	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Podophyllin		Treatment of Genital Warts	No data	
Potassium Chloride	K-Dur		Compatible	
Procainamide			Compatible	
Prochloperazine			Compatible	
Promethazine			With caution	
Propanolol			Compatible	
Propoxyphene			Compatible	
Pseudoephedrine			Compatible	
Pyrantel Pamoate			No data	
Pyridostigmine			Compatible	
Pyrimethamine			Compatible	
Quinapril	Accupril	Antihypertensive	Compatibility unknown	Classified C first trimester, D second and third trimesters
Quinidine			Compatible	
Ramipril	Altace	Antihypertensive	Not recommended by drug manufacturer	Classified C first trimester, D second and third trimesters
Repaglinide		Antidiabetic	Contraindicated	
Reserpine		Antihypertensive Agent	Compatible	
Rifampin		Antituberculosis Agent	Compatible	
Risperidone	Risperdal	Antipsychotic	No data	
Rofecoxib	Vioxx	Nonsteroidal Antiinflammatory	No data	
Salmeterol	Serevent	Bronchodilator	No data	
Sumatriptan			Compatible	
Spironolactone			Compatible	
Sulfapyridine/ Sulfisoxazole			Contraindicated	
Temazepam			Compatible	
Terfenadine			No data	
Theophylline			Compatible	
Thioridazine			Compatible	
Timolol			Compatible	
Tinidazole			Contraindicated	
Tolbutamide			Compatible	
Tolmetin			Compatible	
Tramadol			Not recommended	No adequate human studies
Triamcinolone Acetonide	Azmacort	Corticosteroid	No data	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Triamterene	Dyazide	Antihypertensive	No data, contraindicated	
Trifluoperazine			Compatible	
Tri-methobenzamide			Compatible	
Trimethoprim/ Sulfamethaxazole			Compatible	
Triprolidine			Compatible	
Vaccine, Cholera			Compatible	
Vaccine, Haemophilus B			Compatible	
Vaccine, Hepatitis A			Compatible	
Vaccine, Hepatitis B			Compatible	
Vaccine, Influenza			Compatible	
Vaccine, Meningococcus			No data	
Vaccine, Plague			No data	
Vaccine, Pneumococcal			Compatible	
Vaccine, Poliovirus Inactivated			No data	
Vaccine, Poliovirus Live			No data	
Vaccine, Rabies			No data	
Vaccine, Rubella	Meruvax		With caution	Avoid pregnancy for three months following vaccination
Vaccine, Typhoid			No data	
Vancomycin			No data	
Venlafazine	Effexor	Antidepressant	Contraindicated	
Verapamil			Compatible	
Vitamin B12			Compatible	
Zidovudine			Contraindicated in HIV infection	

Category D: Positive evidence of human fetal risk exists, but the benefits of use during pregnancy may be acceptable despite risk.

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
ACE Inhibitors	Enalapril, Cataopril Lisinopril	Antihypertensive	Compatible	Classified D second and third trimesters, C first trimester
Alprazolam	Xanax	Antianxiety	Contraindicated	
Amitroptyline	Elavil	Antidepressant	Compatible, effect on infant unknown	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Aspirin		Nonsteroidal Antiinflammatory Agent	With caution	Classified D in standard dose, C in low dose
Atenolol	Tenormin	Antihypertensive	Compatible	Intrauterine growth retardation if started in second trimester
Azathioprine	Imuran	Antineoplastic	No data	
Barbituates			With caution	
Benazepril	Lotensin	Antihypertensive	Compatible	Classified D second and third trimester, C in first trimester
Bleomycin		Antineoplastic	No data	
Bumetanide	Bumex	Diuretic	Contraindicated	
Carbimazole		Antithyroid Agent	With caution	
Captopril		Antihypertensive	Compatible	Avoid during pregnacy, associated with intrauterine growth retardation
Chlordiazepoxide	Librium	Sedative	Contraindicated	
Chloropropamide		Antidiabetic	With caution	
Chlorothiazide	Diuril	Diuretic	Compatible	
Cisplatin		Antineoplastic	With caution	
Clonazepam	Klonopin	Anticonvulsant	Contraindicated	
Colchicine		Treatment of gout	Contraindicated	
Cyclophosphamide	Cytoxan	Antineoplastic Agent	Contraindicated	
Dextro-amphetamine			Contraindicated	
Diazepam			With caution	
Dicumarol			Compatible	
Divalproex	Depakote	Anticonvulsant	Compatible	
Doxorubicin			Contraindicated	
Doxycycline			Compatible	
Enalapril	Vasotec	Antihypertensive	Compatible	Classified D second and third trimesters, C first trimester
Fosinopril		Antihypertensive	Not compatible according to drug manufacturer	Classified D second and third trimesters, C first trimester
Hydro-chlorothiazide		Diuretic, Antihypertensive	No data	
Hydrocodone	Vicodin	Narcotic Analgesic	No data	Also classified B

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Hydromorphone	Dilaudid	Narcotic Analgesic	Compatible	Also classified B
Imipramine	Tofranil	Antidepressant	With caution	
Indomethacin	Indocin	Nonsteroidal Antiinflammatory Agent	Compatible	Also classified B
Irbesartan	Avapro	Antihypertensive	No data	Classified D second and third trimesters, C first trimester
Kanamycin			Compatible	
Lisinopril	Prinivil, Zestril	Antihypertensive	No data	Classified D second and third trimesters, C first trimester
Lithium			Contraindicated	8% risk of serious cardiovascular anomaly, 2.7% risk of Ebstein anomaly
Lorazepam			With caution	
Losartan	Cozaar	Antihypertensive	No data	Classified D second and third trimesters, C first trimester
Medroxy-progesterone			Compatible	
Meperidine			Minimal dose	Also classified B
Meprobamate			Contraindicated	
Mercaptopurine		Immino-suppressant	No data	
Methadone		Narcotic	With caution	Also classified B
Methotrexate		Immuno-suppressant	No data	
Methimazole			With caution	
Methotrexate	Methotrex, Rheumatrex	Antineoplastic Agent	Contraindicated	
Morphine		Narcotic	Compatible, inhibits milk	Also classified B
Nortriptyline			No data	
NSAID			Compatible	Classified D near term, B or C in early pregnancy depending on compound
Penicillamine			Contraindicated	
Phenobarbital			With caution	
Phenytoin		Anticonvulsant	Compatible	
Potassium Iodide			Contraindicated	
Primidone			With caution	

Generic Name	Brand Name	Drug Type	Breastfeeding	Additional Notes
Progesterone			Compatible	
Propylthiouracil			With caution	
Quinapril	Accupril	Antihypertensive	Compatibility unknown	Classified D second and third trimesters, C first trimester
Ramipril	Altace	Antihypertensive	Contraindicated according to drug manufacturer	Classified D second and third trimesters, C first trimester
Secobarbital			Compatible	
Sulfasalazine			With caution	Classified D near term due to risk for kernicterus, B in early pregnancy
Tetracyclines			Compatible	
Tobramycin			Compatible	
Vaccine, Yellow Fever			No data	Avoid in first trimester
Valproic Acid			Compatible	Incidence of spina bifida after first trimester exposure approx. 1%
Vitamin D			Compatible	Also classified A
Warfarin	Coumadin	Anticoagulant	Compatible	

Category X: Human or animal studies indicate fetal abnormalities due to drug use during pregnancy. The risk to the fetus outweighs any possible benefit.

Generic Name		Drug Type	Breastfeeding	Additional Notes
Aminopterin			No data	Multiple gross anomalies, fetal death, postnatal growth retardation, craniofacial abnormalities
Atorvastatin	Lipitor	Antilipemic	No data	
Clomiphene	Clomid, Serophene	Nonsteroidal Ovulatory Stimulant	No data	
Cocaine			Contraindicated	Classified X as an illicit drug, otherwise C
Contraceptives, oral			Compatible	
Dienestrol			No data	Cardiovascular defects
Diethylstilbesterol			No data	

Generic Name		Drug Type	Breastfeeding	Additional Notes
Dihydro-streptomycin			No data	Hearing loss
Disulfiram			No data	Spontaneous abortion, club feet
Ergotamine			Contraindicated	Spontaneous abortion, CNS symptoms, Poland syndrome
Erythromycin Estolate			With caution	
Ethanol			Minimal dose	
Etretinate			No data	
Estrogens			No data	
Fluvastatin	Lescol	Hyperlipidemia	No data	
Gallium-69			Contraindicated, radioactivity in breast milk for two weeks	
Gaseous Anesthetics			No data	Spontaneous abortion
Iodine-125			Contraindicated, radioactivity in breast milk for two weeks	
Iodine-131			No data	Cretinism, hypothyroidism
Isotretinoin	Accutane	Skin and Mucus Membrane Agent	Contraindicated	16% spontaneous abortion, 19% major malformations
Methyltestosterone			No data	
Misoprostol			Contraindicated	
Nicotine			Contraindicated, decreased milk production	
Premarin			Contraindicated	
Progestins			No data	
Quinine			No data	Mental retardation, fetal death
Raloxifene	Evista	Selective Estrogen Receptor Modulator	Contraindicated	
Simvastatin	Zocor	Antipemic Agent	No data	

Generic Name		Drug Type	Breastfeeding	Additional Notes
Technitium-99m			Contraindicated, radioactivity in breast milk for three days	
Thalidomide			No data	Limb defects, anomalies of cardiac, renal, and gastrointestinal systems
Trimethadione			No data	
Vaccine, Measles			No data	Avoid pregnancy for three months following vaccination
Vaccine, Mumps			No data	Avoid pregnancy for three months following vaccination
Vaccine, TC-83	Venezuelan Equine Encephalitis		No data	Avoid pregnancy for three months following vaccination
Vitamin A			Compatible	Classified X in high doses, otherwise A

OBJECTIVE-2

APPENDIX - B TRACKING LOG

RELATIONSHIP BETWEEN THE TRACKING LOG AND THE SCREENING & EXCLUSION FORM

The Tracking Log is based on, and organized around, the paper version of the Screening & Exclusion Form. The Tracking Log contains the section titles and each of the individual exclusion criteria contained within the paper version of the Screening & Exclusion Form. A check (✔) of an individual exclusion criterion variable in the Tracking Log indicates the cause of the exclusion for the child.

The Tracking Log is used to track the contact, screening, scanning, behavioral testing and exclusion of potential Objective-2 subjects. Obtaining this type of information is important for comprehensive characterization of our sample, for documenting the recruitment progress of the PSC sites, and for preparing reports for the NIH. The Objective-2 Tracking Log for each PSC site is to be submitted to the CCC weekly. ***It is recommended that you read this Guide prior to using the Tracking Log.***

Only one exclusion criteria needs to be achieved to exclude a child. Therefore, users should **not** enter multiple exclusions for a child in the Tracking Log. If multiple exclusions happen to be obtained for a child, only enter the first exclusion item that is marked "YES" on the paper version of the Screening & Exclusion Form (e.g., if a child is excluded for an item in the 'Pregnancy Section' and also is excluded for an item in the 'Birth Section', **only** the exclusion item for the 'Pregnancy Section' should be entered into the Tracking Log).

Additionally, for each subsequent time-point, a new screening is conducted with the family (i.e., a new Screening and Exclusion paper form is filled out), and a new record is added to the Tracking Log for that child. Do not modify the Tracking Log record from a previous time-point for a subsequent time point.

GETTING STARTED

Saving the Log

The Tracking Log was sent to you as an e-mail attachment file (or as a file on a CD), and you will need to save the file to a computer hard drive or network drive before you open it. DO NOT open the file and begin working on the Tracking Log without first saving the file to your hard or network drive. Otherwise, data entered into the Tracking Log may be lost.

Reporting Problems

While every effort has been made to ensure that the Tracking Log is free of errors and compatible with your system, some errors may occur. If you have any problems with the MRI Objective 2 Tracking Log, contact the CCC.

WHAT IS THE TRACKING LOG

The MRI Objective 2 Tracking Log is designed to include data for all potential, successful and excluded subjects. This includes those subjects screened and excluded (even if only screened by medical record review), as well as those successfully completing the neurological exam, behavioral testing, and brain scan.

The Tracking Log consists of eleven Tracking Log Forms and a Tracking Log Table. Using the Forms, you can view, add, or update information about all of your screened, refused, excluded, and successful subjects. The Table allows you to view all the information entered about all the children in the Tracking Log. Do not make any modifications directly to the Tracking Log Table. Instead, make any changes or updates to a subject's record using the appropriate Tracking Log Form.

Essential Information for the Tracking Log

Initial Contact with Potential Subjects

Objective-2 has three basic options for making initial contacts with potential subjects: (1) Medical Record Review, (2) Referral, and (3) Person-to-Person.

Medical Record Review
Medical Record review allows sites to go through medical records to determine if a child is eligible to be considered as a potential subject. For children excluded during Medical Record Review, it is not necessary to contact the parent(s) to obtain signed Consent (unless required by your site's IRB).

Referral
Referrals include any situation where the child's contact information (e.g., provided by Obective-1, physicians, clinics, private citizens, etc.) is provided to you.

Person-To-Person
For this option, a PSC site makes initial contact with a potential subject via telephone, letter, or face-to-face contact (e.g., directly contacting co-workers, relatives, neighbors, subjects in your other studies, etc.).

Adding Initial Information to the Tracking Log

Once you have received initial information about a potential subject (regardless of the source) you need to begin the screening process for the subject. This Guide uses the term "screening" to indicate the exclusion information contained within the paper version of the Screening & Exclusion Form and the FIGS. Behavioral testing is used to indicate the Bayley, PLS-3, handedness, and so on. However, some behavioral testing items serve as "screening" tests. These are listed on the Screening and Exclusion form.

There are two basic ways that the subject will be recorded. If the subject has not been contacted and/or has not been excluded, then you will need to record their information on the Child Code Form (see below). If the subject has been excluded, then the reason for exclusion is entered into the

appropriate Tracking Log Form (see below). If the child is excluded during the medical record review, the reason for exclusion is entered into the appropriate Form of the Tracking Log.

Entering Data in a Form

There are primarily three circumstances under which you will enter information in the Tracking Log.

- The child has not been excluded because screening has not begun or screening is in progress. (*For these children, you will need to add a new record to the Child Code Form for the child).*
- The child has already been screened and found to have met an exclusionary criterion. (*In this instance, you should go directly to the appropriate exclusion Form in the Log, add a new record for the child, and enter all of the required information [Child Code and Exclusion] into that Form).*
- The child has new information available and their record needs to be updated in the Tracking Log. *(In this instance, you should go directly to the appropriate Form and make any necessary changes)*.

Child Code

The Child Code is a summary of the unique identifiers for each child that is used in the Tracking Log. In addition to being available in the Child Code Form, each child's code automatically appears on each of the other Forms (e.g., Demographic Form or Delivery Form) making up the Tracking Log. The Child Code for a child can also be entered directly into one of the exclusion Forms at the same time that the exclusion is being input to the Form. The Child Code includes:

- Scan Number (1, 2, or 3)
- First three (3) letters of child's last name
- Child's zip code
- Method of contact (Medical Records, Referral, or Person-To-Person)
- Date Screening Began
- PSC site

For clarification, in this Guide Child Code refers to the set of information that serves as a unique identifier for each child, and Child Code Form refers to the specific screen in the Tracking Log used to enter the Child Code into the Tracking Log. Each Form in the Tracking Log contains the Child's Code. This makes it very easy to identify the child at a later date and enter additional information about a child who has already been partially screened or excluded.

Refused to Participate in the Study or Parts of the Study

From time to time, a child or the parents may refuse to sign a Consent form, refuse to answer important exclusionary questions, or refuse to undergo the neurological exam, behavioral testing, or the brain scan. This refusal information is entered into the Tracking Log. The Tracking Log includes a Refused box (input a check-mark to indicate refusal), and a "Refused Comments" text box (see Figure 8) where you write in the reason for the refusal (e.g., "would not give/sign Consent," "did not return telephone calls or letters," "refused to complete exclusionary screening questions," "refused behavioral testing, neurological exam, or brain scan," etc.).

Reminder: If a potential subject has already been assigned a PSC/DCC ID prior to refusing, you will also need to indicate that the child/parent has refused in the web database.

Wrong Age

Wrong Age is not a variable in the Tracking Log, and Wrong Age should never be entered into the Tracking Log as an exclusion or refusal. For example, if you are looking for a 6-month old child, and find a family that has no children or only a 12-month old child, do not enter that data into the Tracking Log. Of course, if you decide to pursue screening of the 12-month child, data for that child would be entered into the Tracking Log. In fact, sites are encouraged to 'age up' children in order to fill cells.

Visit/Time Points

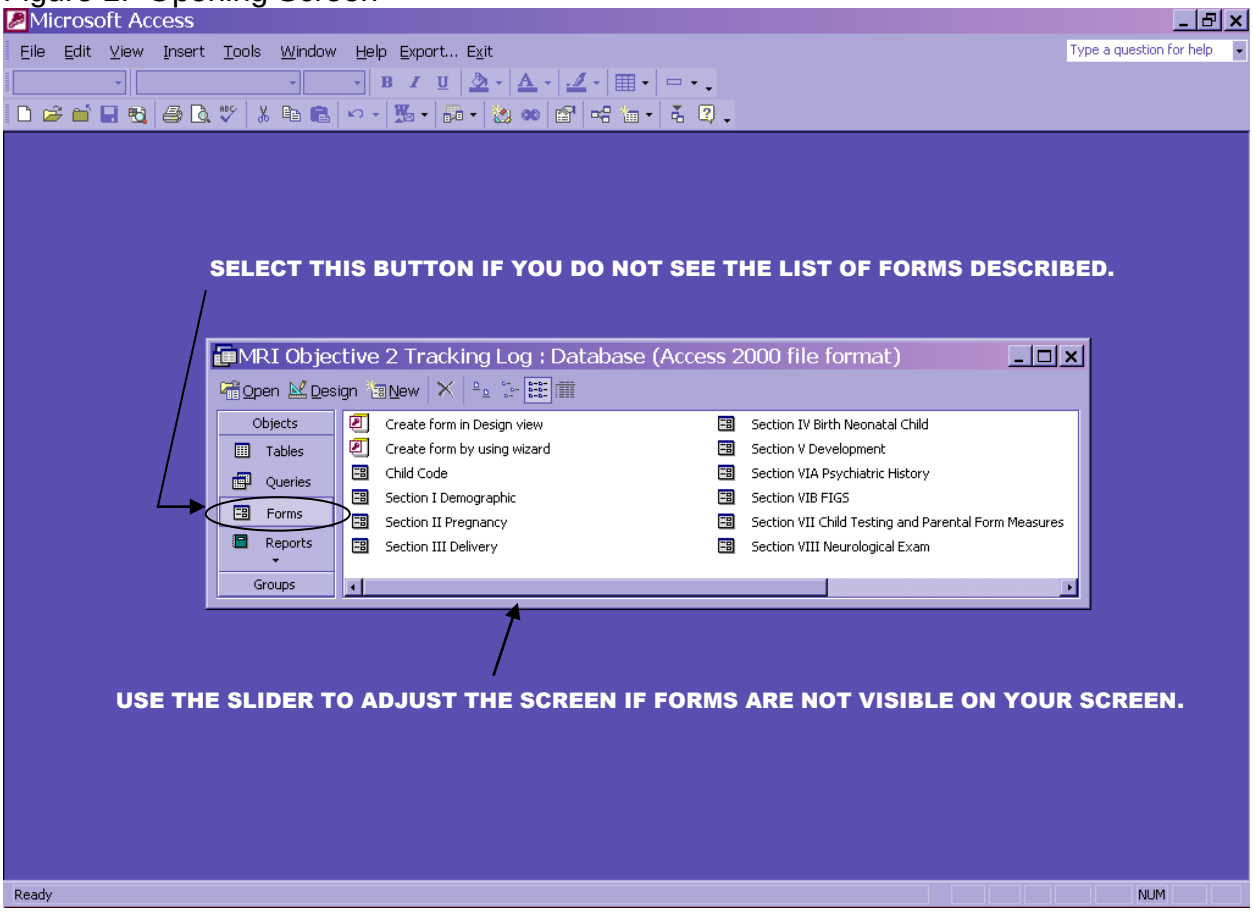
Objective-2 uses "time point" to describe each opportunity for a scan and behavioral testing for each child (e.g., newborn, 3 months, 48 months, etc.). There may be multiple visits involved in a time point (e.g., behavioral testing occurs on one day, neurological exam occurs on a second day, and the scan occurs over three days). Each of these visits would be combined under one time point label, corresponding to the child's targeted test age.

The Tracking Log only records multiple attempts at a scan for a time point (i.e., if the time point is split up so that there are two days of behavioral testing, and one attempt at the scan, then there should only be one entry in the Tracking Log for that time point). Multiple visits for a single time point can be matched utilizing the "Child Code" and "Targeted Test Age."

Using the Tracking Log

Open your Tracking Log from its saved location. Your screen should look like Figure 1. If your screen does not look like Figure 1, try clicking on the Forms button of the Tracking Log. If you remain unable to see all of the Forms, use the slider, as indicated in Figure 1, to adjust your screen view left or right.

Figure 1. Opening Screen



The Forms

The Tracking Log is designed to be easy to use. The Tracking Log is divided into eleven forms. In Figure 1 you can see that there is a Tracking Log Form entitled Child Code, as well as nine other Forms that correspond to the main section headings of the paper version of the Screening & Exclusion Form. Finally, there is a Successfully Completed Scans Form (not visible). The eleven Forms are listed below:

1. Child Code
2. Section I Demographic
3. Section II Pregnancy
4. Section III Delivery
5. Section IV Birth Neonatal Child
6. Section V Development
7. Section VIA Psychiatric History
8. Section VIB FIGS
9. Section VII Child Testing and Parental Forms
10. Section VIII Neurological Exam
11. Successfully Completed Scan

For your convenience, a picture of each Form has been included in the text of this Guide.

Adding A New Record

You will need to create a new record for each time a child is screened for a new time point (if a child is excluded before they begin testing, record this as scan-1). Additionally, if there are multiple attempts at a scan for a single time point, each attempt at the scan should be tracked by adding a new record for the child. There are two ways to add a new record in the Tracking Log. One method is to open the appropriate Form (e.g., Child Code Form, Demographic Form, etc.), select Insert from the menu (see Figure 2), and click New Record from the pull down menu.

Figure 2. Menu Bar

A second, faster, method is to open the appropriate Form (e.g., Child Code Form, Demographic Form, etc.) and select the right-most arrow key (i.e., arrow key with *) from the Navigational Bar. You will automatically be moved to a new record and can begin entering new data into the Tracking Log.

The Tracking Log will automatically assign each new record an ID number as soon you begin typing the child's information into the Tracking Log. Record the ID Number where you will be able to locate it again. This number will allow you to quickly locate the child's information for the appropriate time point again in the Tracking Log. Do not enter any data into this area.

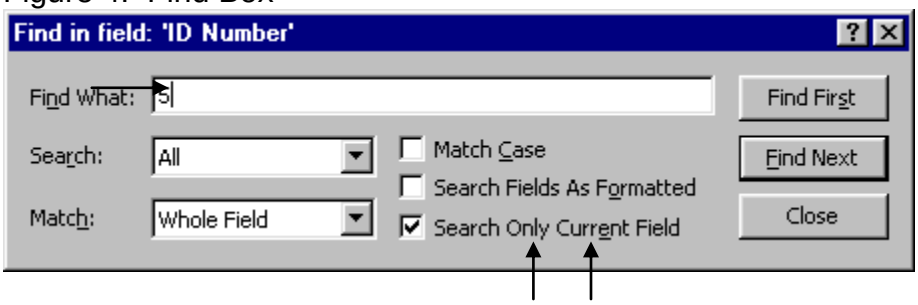
Figure 3. Navigational Bar

Updating Existing Records

Many times you will have enough information about the child to complete the Child Code Form before screening and testing have been completed. For instance, you may have a child who has successfully completed scan-1 and is returning for scan-2. You can complete the Child Code Form for scan-2 as soon as you begin screening the child. Once the screening for scan-2 is complete, you may need to go back into the child's record and modify or update information about the child. In order to do that, you will need to retrieve the child's scan-2 record. In order to retrieve the child's record:

1. Open the appropriate Form (e.g., Section VIB FIGS)
2. Click on the ID Number box
3. Press CTRL-F
4. Make sure 'Search Only Current Field' and 'Match Whole Field' are selected (Figure 4)
5. Enter the ID Number you are searching for in the 'Find What' space (Figure 4)
6. Click 'Find First'

Figure 4. Find Box

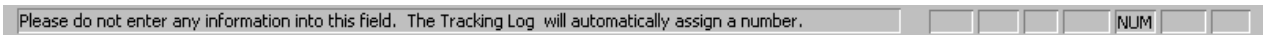


You can also use the arrow keys (Figure 3) at the bottom of the screen to scroll through the various records, but this may become cumbersome if there are multiple records in the Tracking Log.

Information Bar

The Tracking Log provides you with additional information at the bottom of the screen about the type of information that is valid for most variables. An example is shown below in Figure 5. This message appears when the cursor is placed in the 'ID Number' box of the Child Code Form. The full Form can be seen in Figure 8.

Figure 5. Information Bar

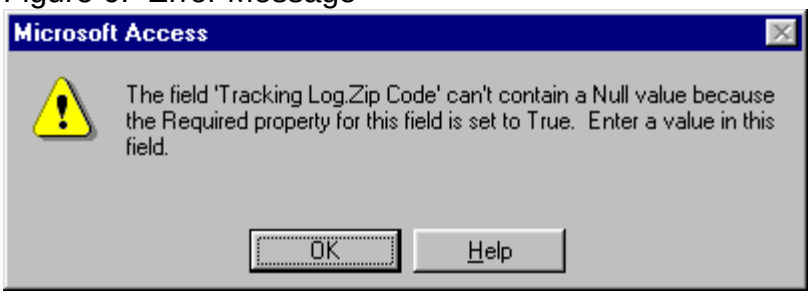


Required Information

In order to save a child's record in the Tracking Log, you must know (1) the child's Scan number, (2) the 'First Three Letters' of the Child's Last Name (3), the child's Zip Code (4), Method of Contact, and select the (5) PSC Site.

If you forget to enter required information, the Tracking Log will prompt you with an 'error message' similar to the one in Figure 6. The message in Figure 6 means that the Zip Code has been left blank. Once information has been entered into a Form and saved, the information is automatically included on all other Forms.

Figure 6. Error Message

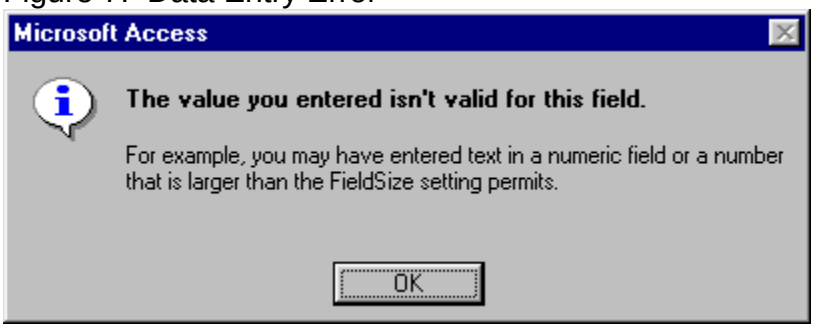


Data Limits

Some fields will only accept certain types of data. For instance, the First Three Letters area will only accept three letters. The zip code area will only accept numbers. Dates must be entered in the following format mm/dd/yy (e.g., 06/02/02). The Tracking Log will put the slashes (/) in automatically for you. Scan number, Method of Contact and PSC Site are drop down menus where you can select

the specific item you need. If you attempt to enter data into field, which does not match the Tracking Log's expectations, you will receive an error message like the one below:

Figure 7. Data Entry Error



While the Forms all function basically the same, there are some unique characteristics of each Form. Following is a discussion of each Form, and an example of what the Form looks like in the Tracking Log.

Forms

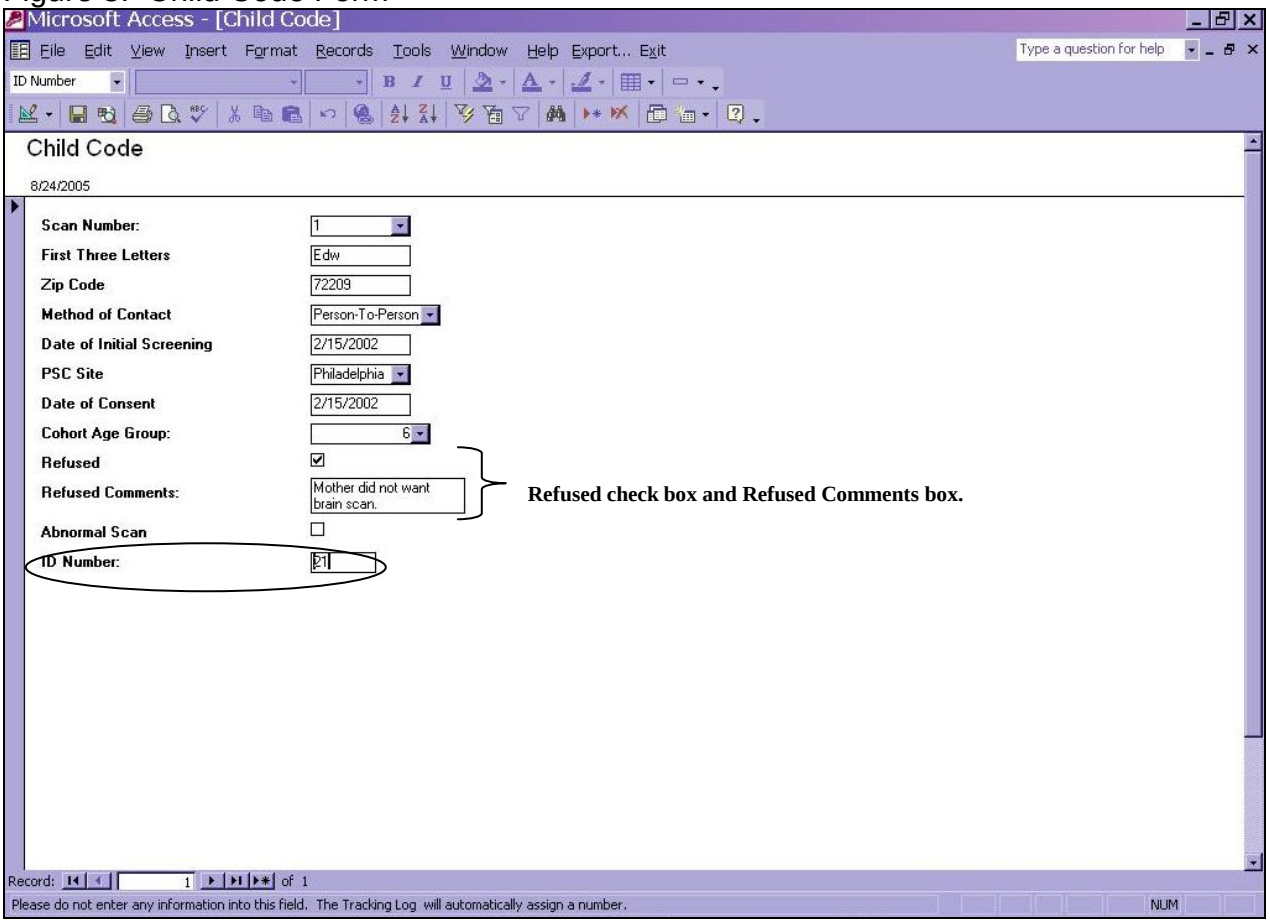
Most forms correspond to an exclusion section of the paper version of the Screening & Exclusion Form. To use the Form, you will need to either add a new record for the child or select the child's current record (please refer to *Adding A New Record* and *Updating Existing Records* for more information on this process).

If this is the first time you have entered information for the child, you will need to enter the Child Code, the Date of Screening, the Date of Consent, and the appropriate exclusionary criterion. If you are updating the child's record, double check the "Child's Code" to ensure that all of the child's information is accurate, and complete the Date of Consent. Finally, select the appropriate exclusion criterion.

Child Code

The Child Code makes up the unique identification code for each screened, refused, excluded or successful child. The Child Code Form (Figure 8) contains the information that makes up each child's unique code.

Figure 8. Child Code Form



The Tracking Log requires that Scan number, First Three Letters, Zip Code, Method of Contact and PSC Site be completed before you will be able to save a child's record. The Child Code Form also includes several areas that are not required to save a child's record, but when appropriate should be completed as soon as possible. These are the Date of Initial Screening, Date of Consent, Date Scan completed, Refused, Refused Comments and Abnormal Scan.

The Refused check box is used if a child or parent refuses to participate in the study at any time or refuses to complete any significant task in order to continue the study (see the *Refused* section for additional information). Following checking the Refused box the Refused Comments area should be used to enter details about the refusal (see Figure 8).

The last item on the Child Code Form is the ID Number. The Tracking Log will automatically assign this number to the child as soon you begin typing the child's information into the Tracking Log. A child will have a different ID Number for each record. Record the ID Number where you will be able to

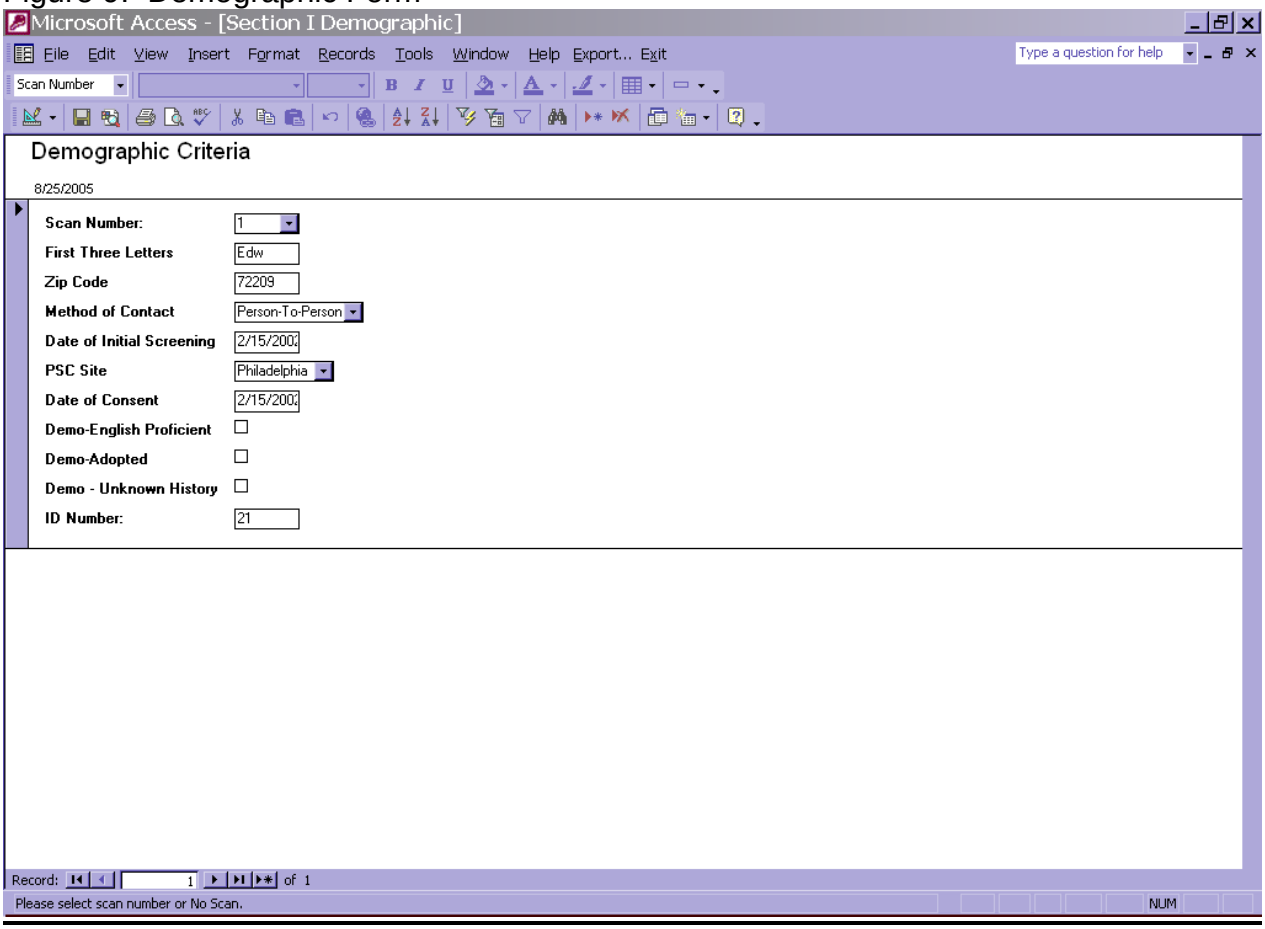
locate it again. This number will allow you to quickly locate the child's appropriate record again in the Tracking Log. Do not enter any data into this area.

To use the Child Code Form, you will need to either add a new record for the child or select the child's current record (please refer to the *Adding A New Record* and the *Updating Existing Records* sections for more information on this process). If you are updating an existing record, double check the information contained in the record to ensure its accuracy. If you are adding a record for a child, you will need to enter the Child Code, the Date of Screening, the Date of Consent, and the appropriate exclusionary criterion.

Section I Demographic

The Section I Demographic Form corresponds to the Demographic Section of the paper version of the Screening & Exclusion Form (see below).

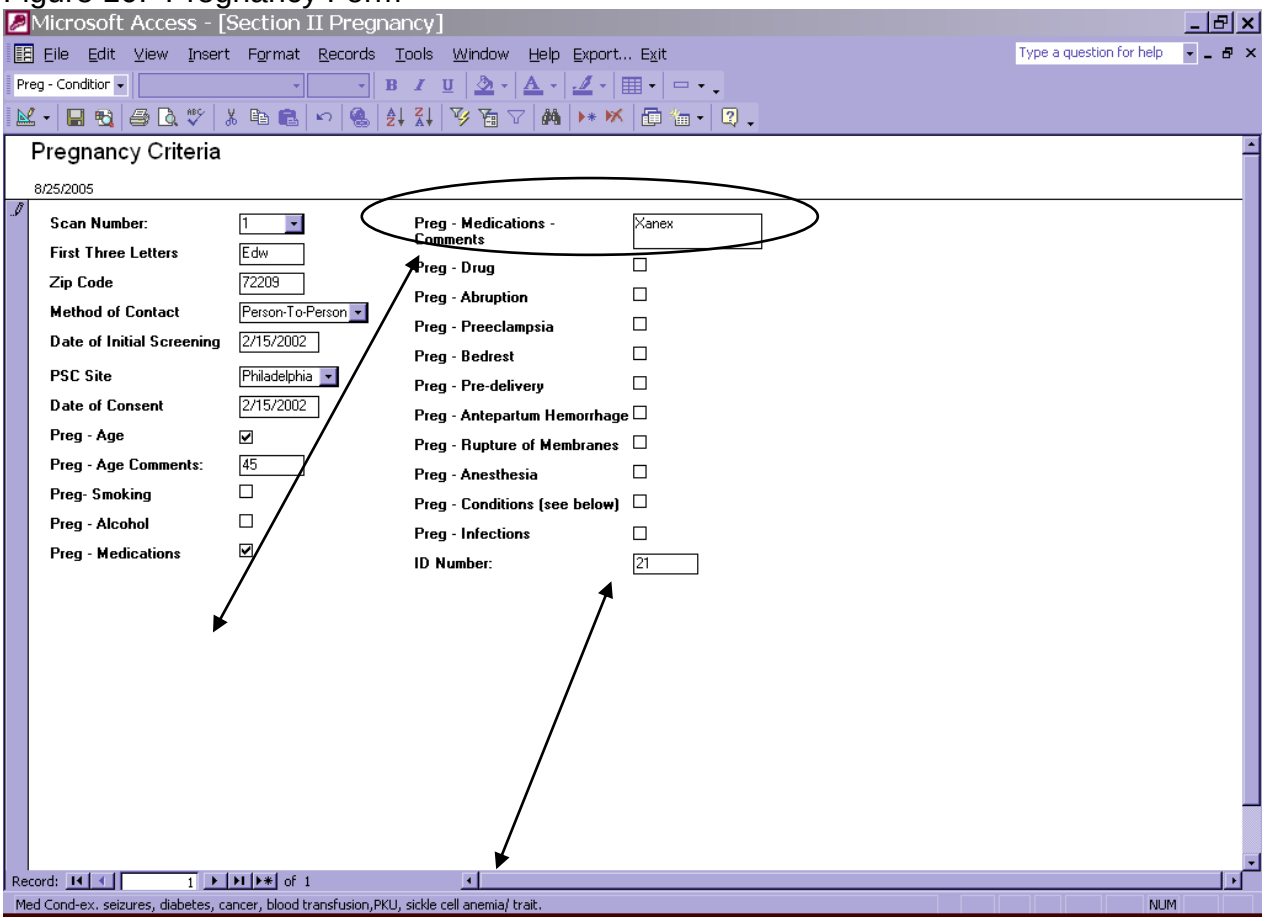
Figure 9. Demographic Form



Section II Pregnancy

This section reflects the Pregnancy Section of the paper version of the Screening & Exclusion Form. An example of the Section II Pregnancy Form can be found in Figure 10.

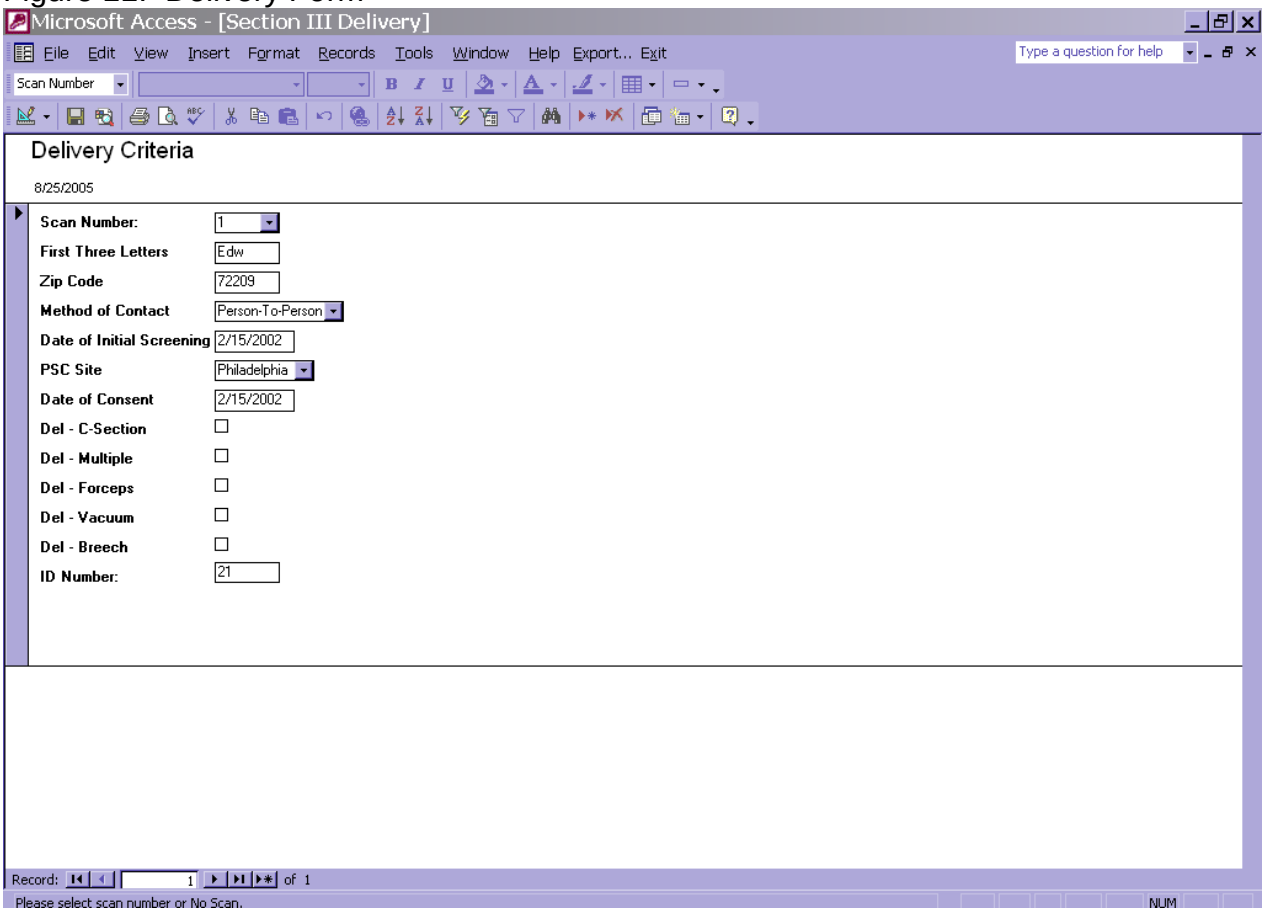
Figure 10. Pregnancy Form



Of special note is the entry setup for both Preg – Age and Preg – Medications. For both of these areas, you will need to place a check in the appropriate box, and indicate the specific details of the exclusion in the appropriate comments area. For instance, in Preg – Medications, the Preg – Medications Comments section indicates the specific medication (Xanex in this example) which made the child ineligible for the study. Finally, the Preg – Conditions (see below) criterion refers the user to the information bar at bottom of the screen. Click the phrase Preg-Conditions to see the information in the bar at the bottom of the screen (Figure 10).

Section III Delivery

Figure 11. Delivery Form

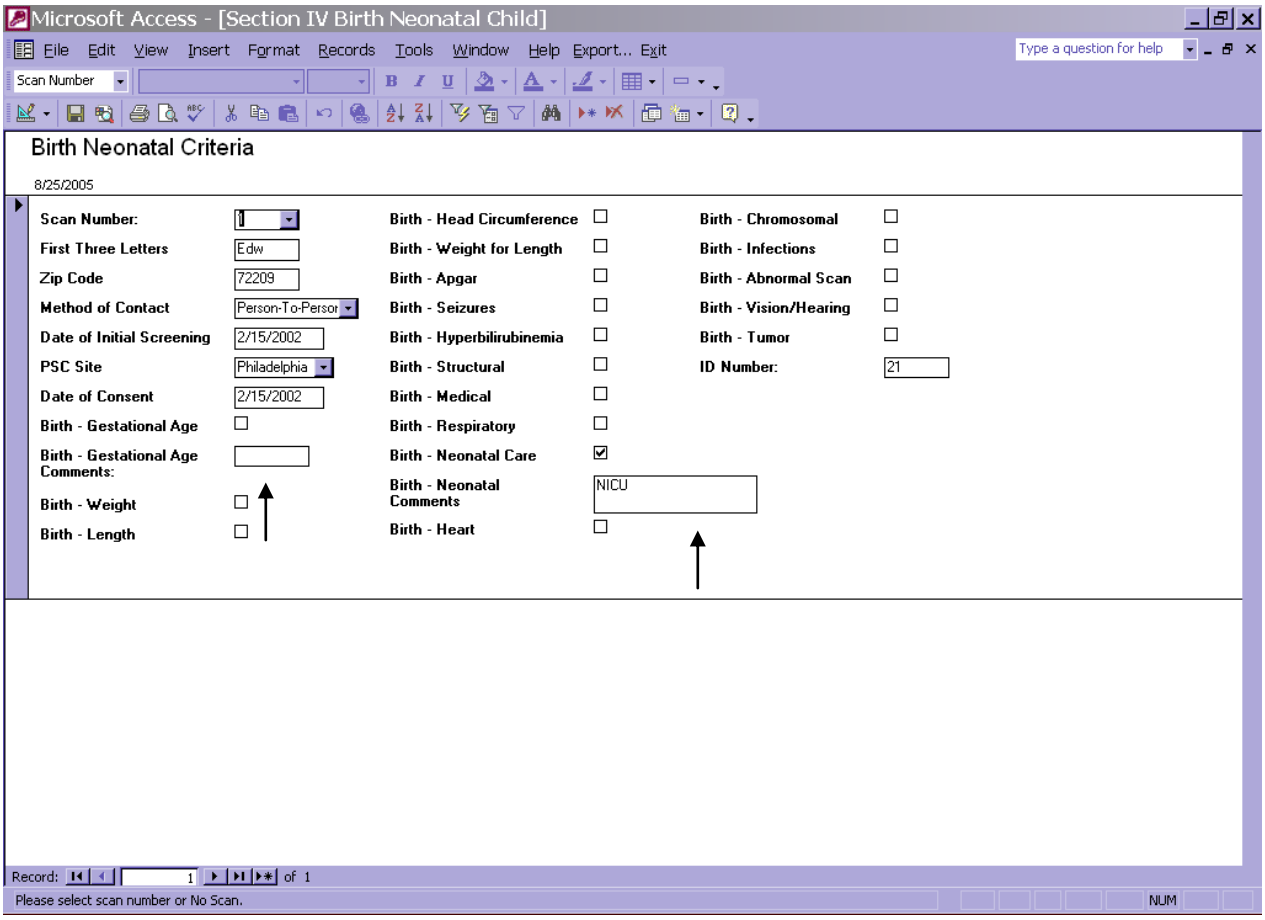


This section is used to indicate any child who has been excluded because of any of the Delivery Exclusion criteria, based on the Delivery Section of the paper version of the Screening & Exclusion Form (see Figure 11).

Section IV Birth Neonatal Child

The Birth Neonatal Form (see Figure 12) is similar to the Pregnancy Form in that there are several areas which include a place to check the excluding factor and a place to provide details of that exclusion.

Figure 12. Birth Neonatal Child Form

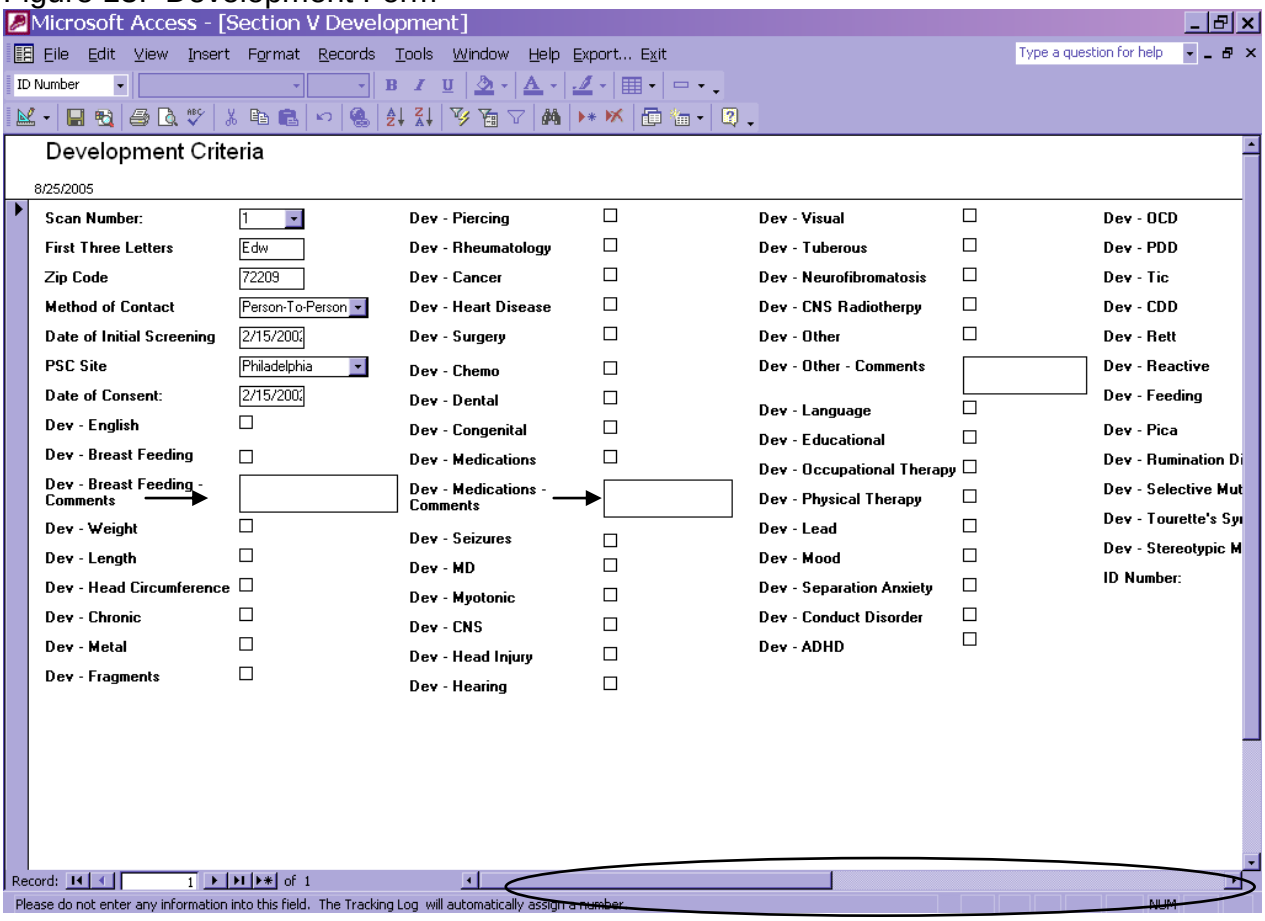


After you have selected the Birth Neonatal Form from the opening screen (see Figure 1), you will need to either add a new record for the child or select the child's current record. Select the appropriate exclusion criterion by putting a check (✔) in the appropriate box.

Section V Development

The Development Form (see Figure 13) mirrors the Development Section of the paper version of the Screening & Exclusion Form. There are several things of note on the Development Form. First, the Breast Feeding, Medications and Other criteria have two parts. They have exclusion check boxes and blanks to include any comments (see Figure 13). In addition, please note that the size of the Form on your screen may necessitate your scrolling left or right with the slider bar in order to see the entire Form (refer to Figure 1 for instruction on scrolling to the left or right).

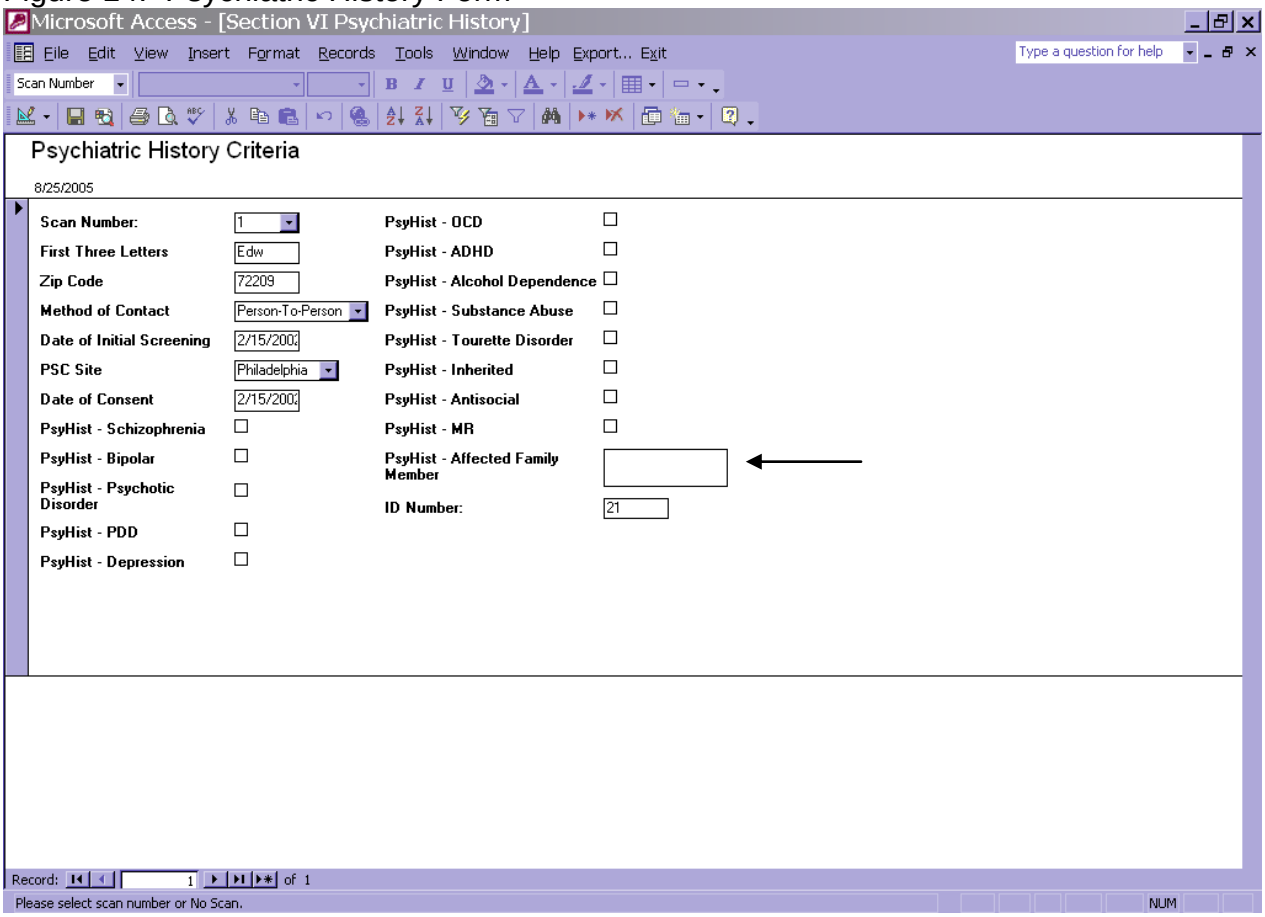
Figure 13. Development Form



Section VIA Psychatric History

Similar to previous sections, this section (see Figure 14) includes a place to indicate additional comments about the child's family. Specifically, there is a place to include the relationship of the person affected with an exclusionary disorder to the child being screened. The Psychiatric History Form is different from the FIGS Form, and the two should not be used inter-changeably.

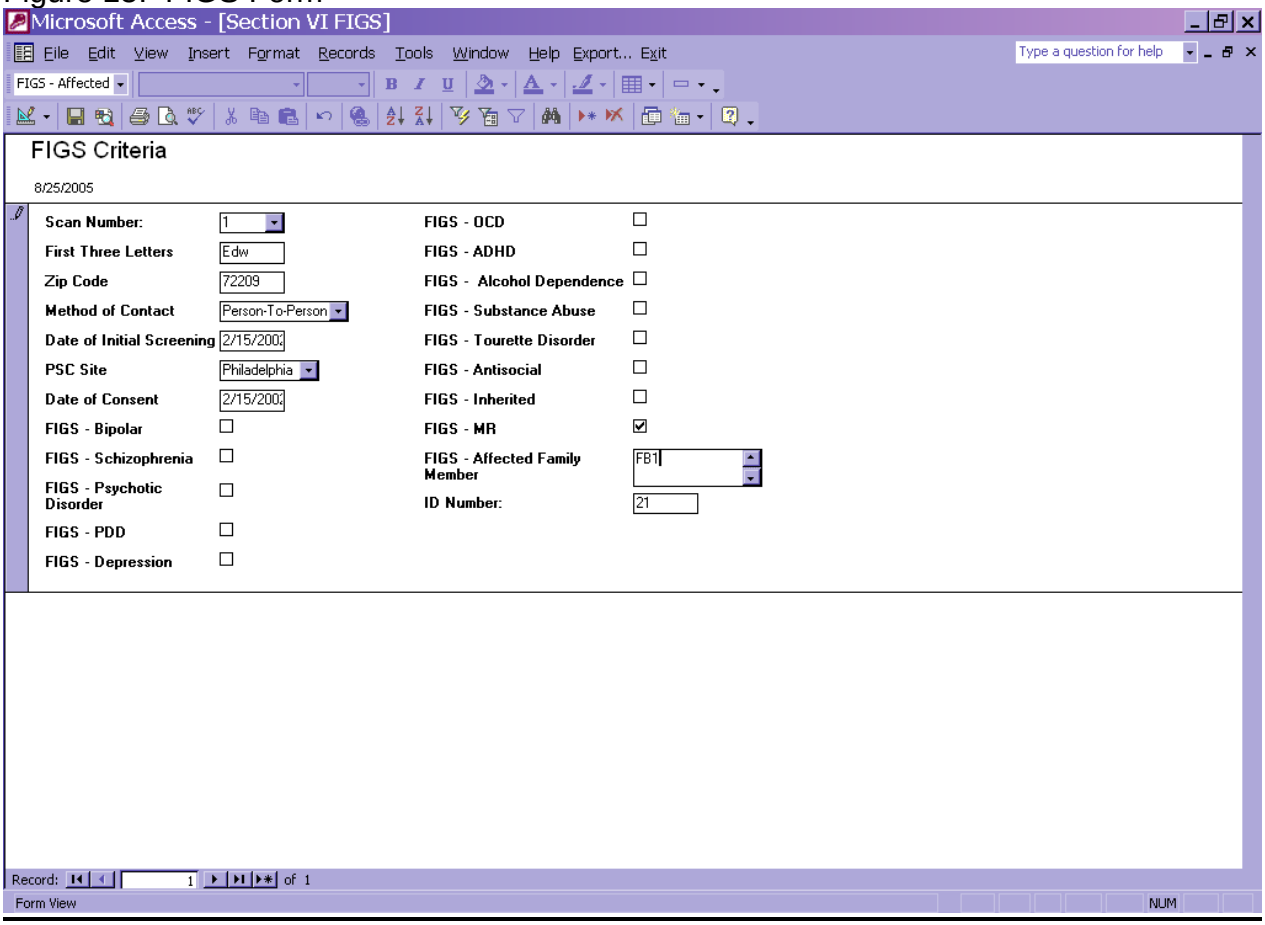
Figure 14. Psychiatric History Form



Section VIB FIGS

If a child is excluded because of the FIGS (see Figure 15) please include the relationship of the person affected with an exclusionary disorder to the child being screened in the text box provided. The FIGS Form (B) is different from the Psychiatric History Form (A) and the two should not be used inter-changeably

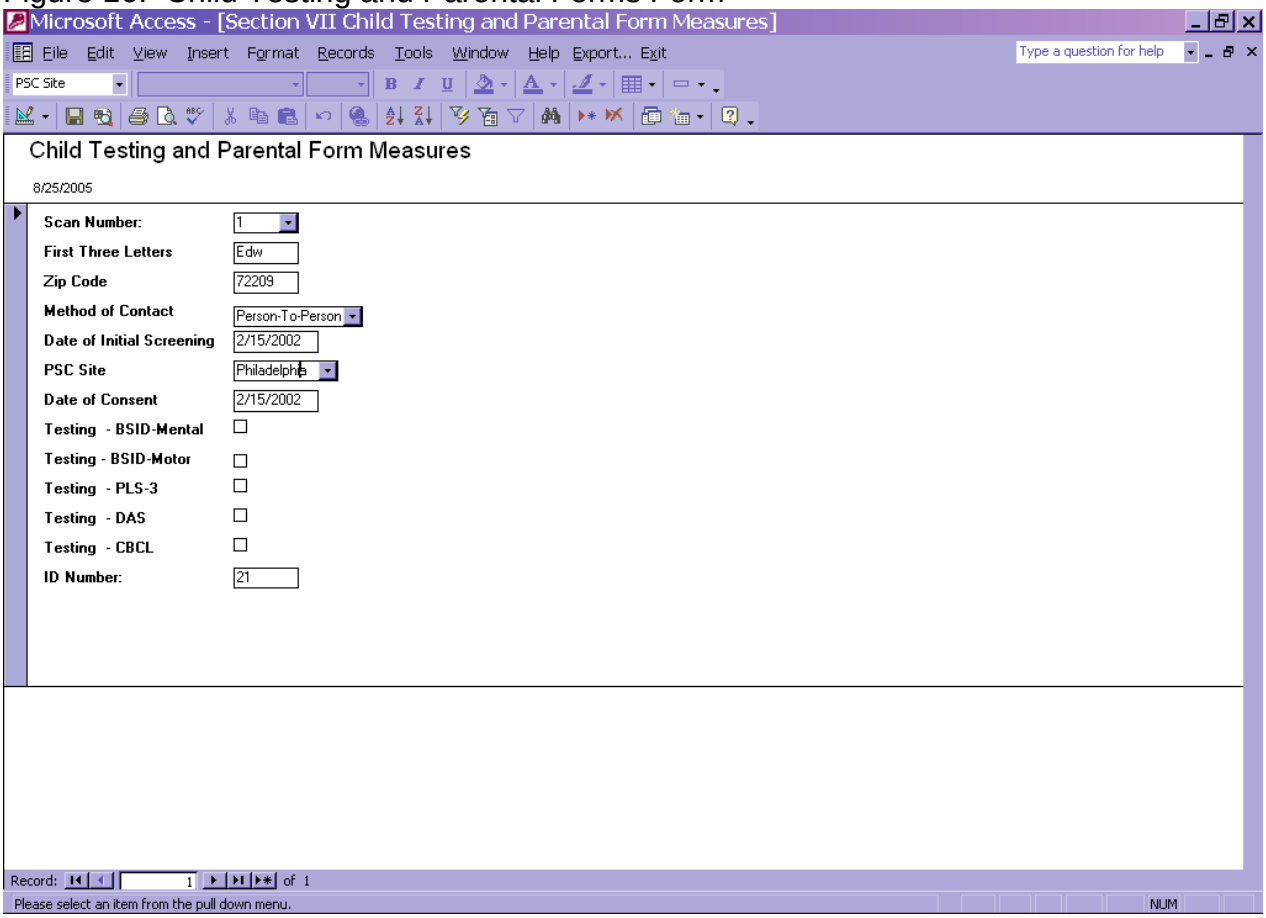
Figure 15. FIGS Form



Section VII Child Testing and Parental Forms

This section reflects the Child Testing and Parental Form (see Figure 16) section of the paper version of the Screening & Exclusion Form. Please note that it is not necessary to record the child's score on test items, only to indicate that the child was excluded by the score on the specific test checked.

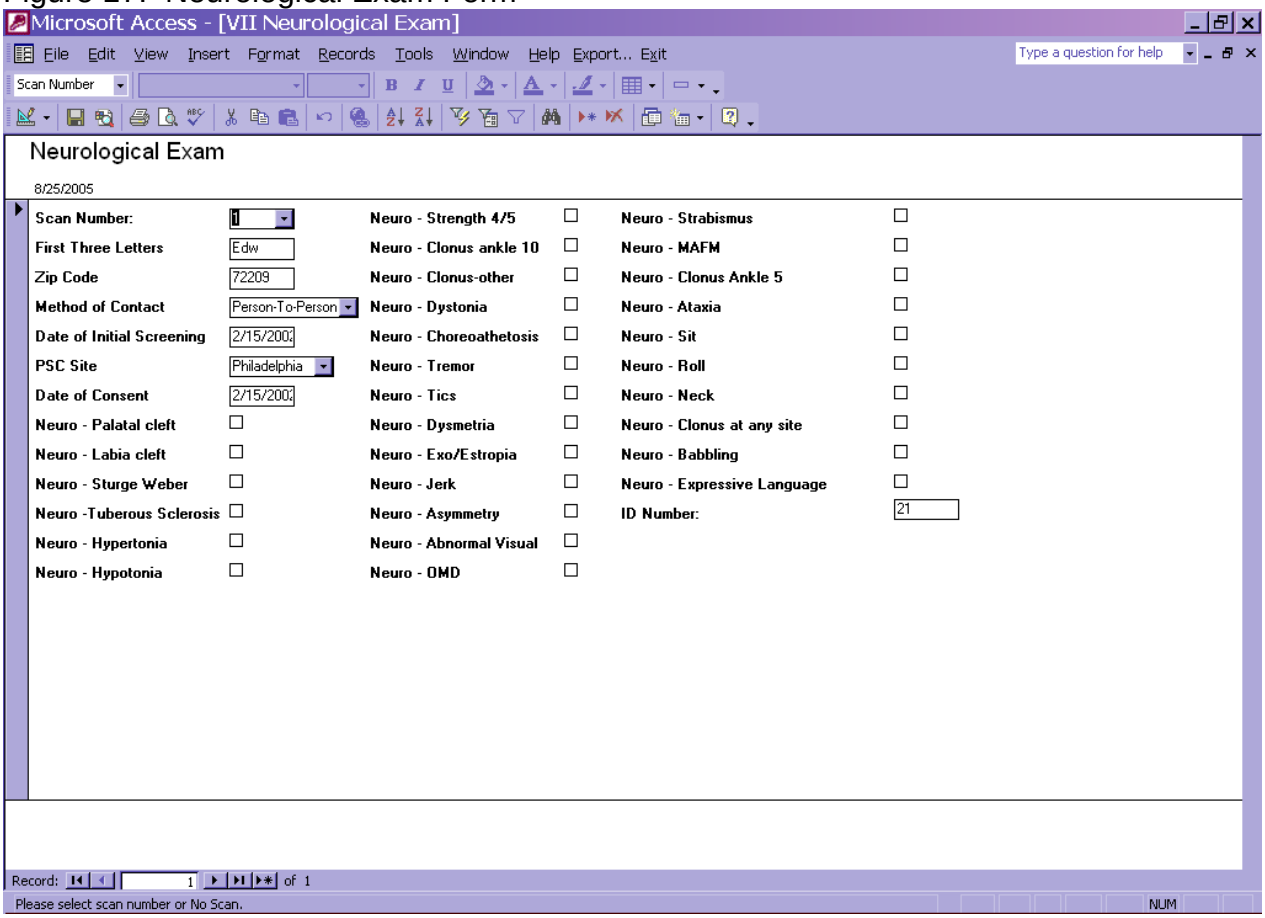
Figure 16. Child Testing and Parental Forms Form



Section VIII Neurological Exam

The Neurological Exam Form (see Figure 17) includes all the exclusion variables for all the age groups on the Neurological Exam (or the paper version of the Screening & Exclusion Form). The variables may appear in a slightly varied order when compared to the Neurological Exam (or the paper version of the Screening & Exclusion Form). Specifically, the exam order for children 0:0-0:1 appears exactly as it does on the paper form, however, after this point any new variables were added to the end. For instance, ">5 beats of clonus at ankles" is not a variable on the 0:0-0:1 exam, but is on the 0:2-0:11 exam. Therefore, it appears after "Markedly Abnormal Facial Movement" area on the Form (MAFM in Figure 17).

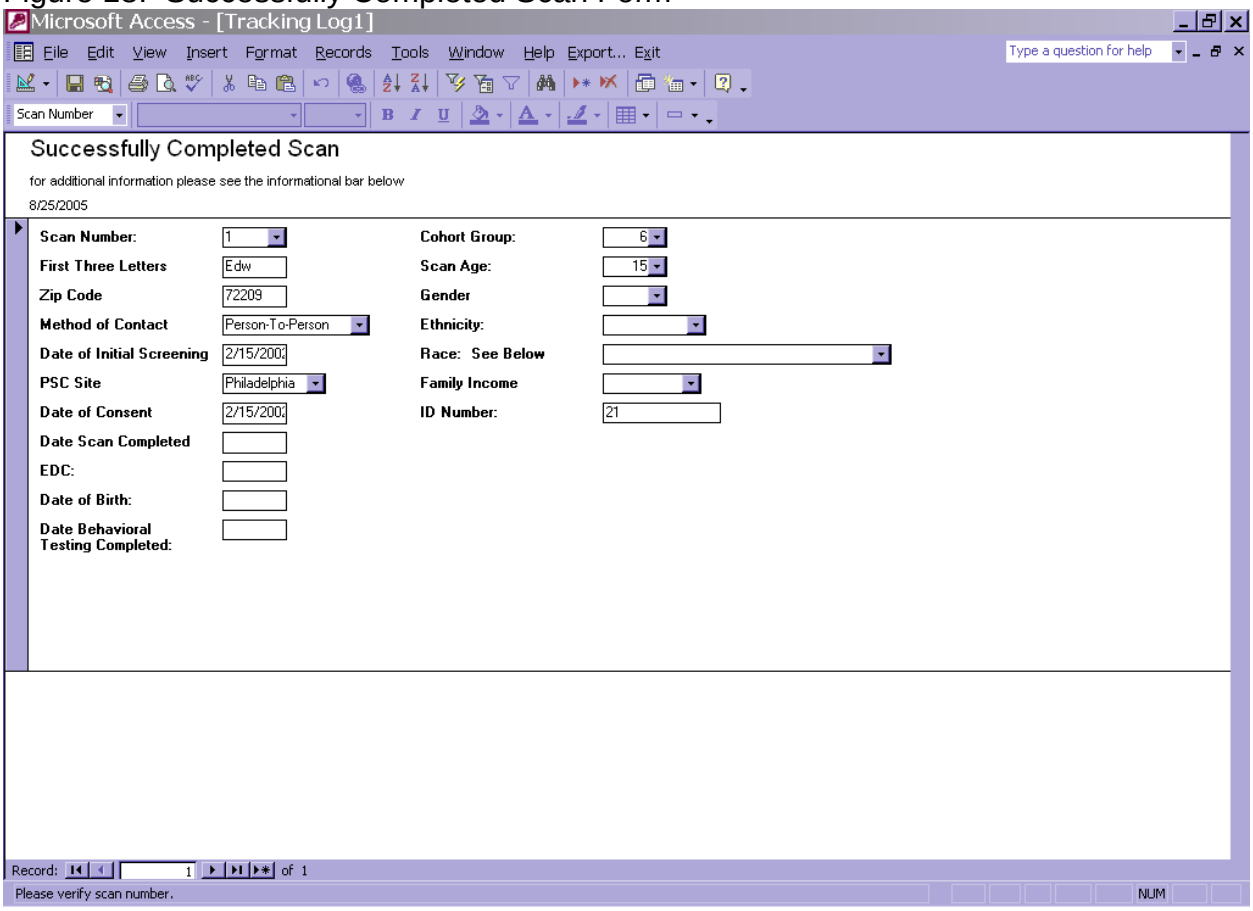
Figure 17. Neurological Exam Form



Successfully Completed Scan Form

This form (see Figure 18) allows for the characterization of our sample. This form should be completed once a child has finished a time point. The pull down menu allows entry for scans 1 through 5. If a child has more than five scans, you can type in the additional number(s) as needed. If no scan is acquired for a particular time point, but the family is screened for the time point, then enter "No Scan" for each record for that time point. When the child is rescheduled choose the next appropriate scan number. For instance, if a child has a scan when they are a newborn, that is Scan Number 1, and you miss their three month scan (normally Scan Number 2), enter "No Scan." The child's six month scan should be entered as Scan Number 2. In addition, you should attempt to complete Scan Number 3 at nine months so that the child has a total of at least three scans.

Figure 18. Successfully Completed Scan Form



EDC, Date of birth and Date Behavioral Testing Completed work similar to all other date fields. These fields should be completed at the end of each time point on one record (the record corresponding to a completed scan and/or the first record of a failed scan for that time point).

This child's Cohort (0, 3, 6, 9, 12, 15, 18, 24, 30, 36, or 48 months) is determined by their age at their FIRST SUCCESSFUL Scan. The child's Cohort (e.g., 3-months) will remain the same throughout all of the child'sr visits; however, their SCAN AGE will change with each subsequent time-point/visit (e.g., 3, 6 and 9 months).

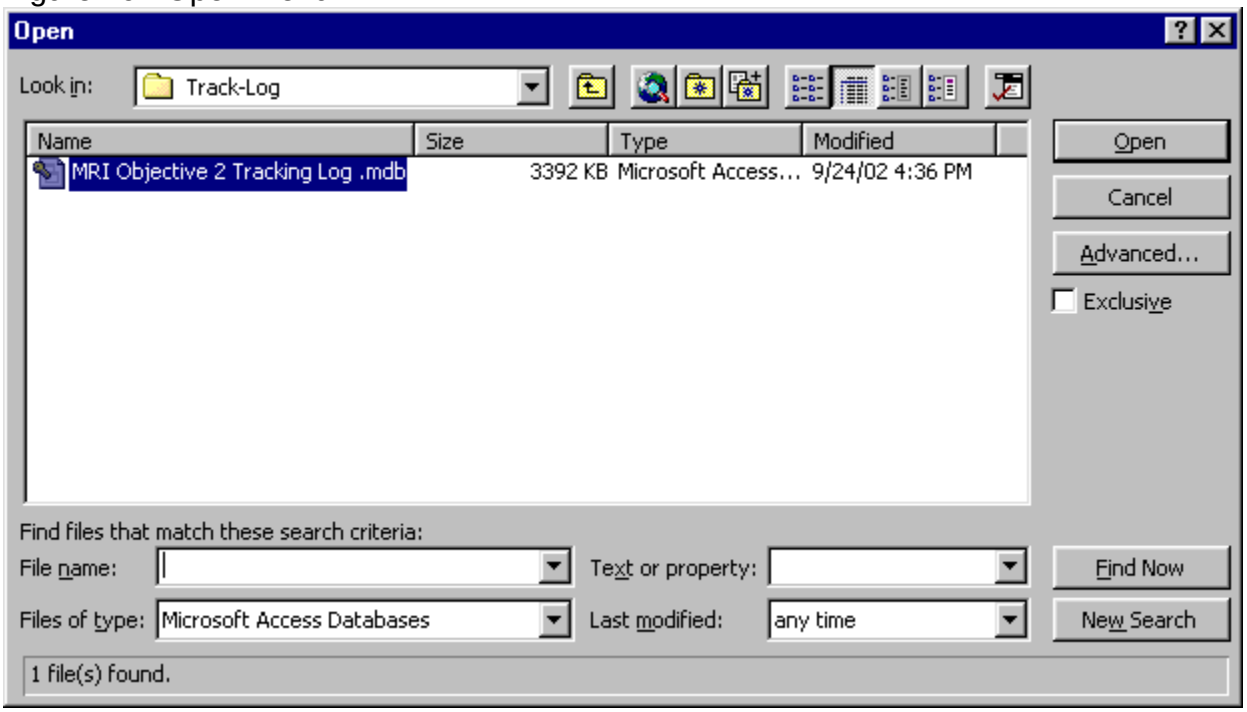
Racial categories and Family Income should be updated from the Family Biographical History form. If only one race is marked, use the drop down menu and select one race. If more than one race category is marked for the child on the 'Family Bio History' Form, then type them in, using the same order they are listed on the Form. For instance, if a family checks "Native Hawaiian or Other Pacific Islander" and "White," then type the full title of both races into the blank provided.

Centralizing Data

Each PSC site is expected to email a copy of their MRI Objective-2 Tracking Log to the CCC on a weekly basis. The CCC will maintain a centralized tracking log of all Objective-2 subjects that have been either screened, excluded, refused or are successful. In order to e-mail your Tracking Log as efficiently as possible, you will need to export the data from your Tracking Log to an Excel File using the following steps.

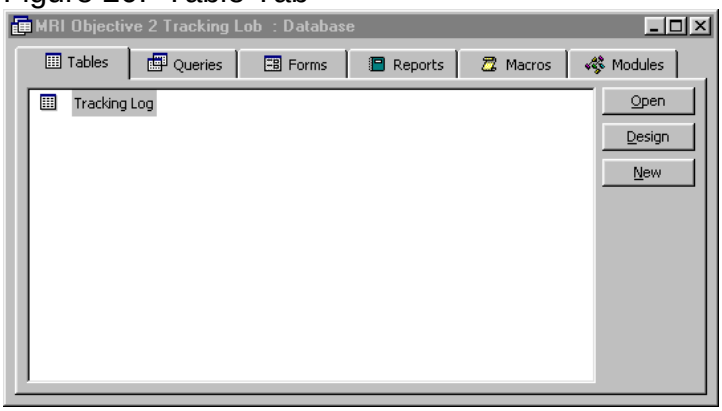
Open your Tracking Log.

Figure 19. Open Menu



Step 1. Click the TABLE tab, select the ***Tracking Log*** file, and click the open button on the right of the box.

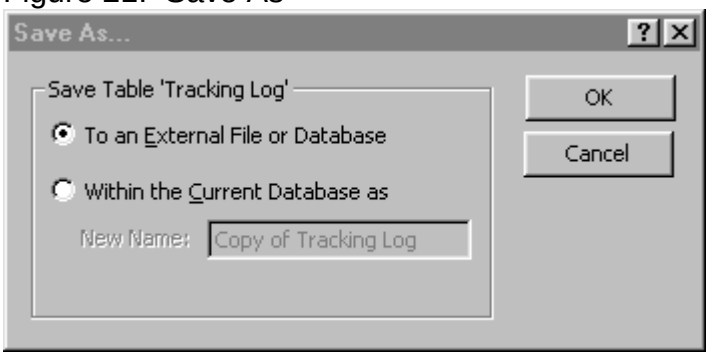
Figure 20. Table Tab



Step 2. Open the FILE menu and select SAVE AS/EXPORT (no picture available). A 'SAVE AS' box will appear (Figure 20).

Step 3. Make sure 'TO AN EXTERNAL FILE ON DATABASE' is selected and then click OK.

Figure 21. Save As



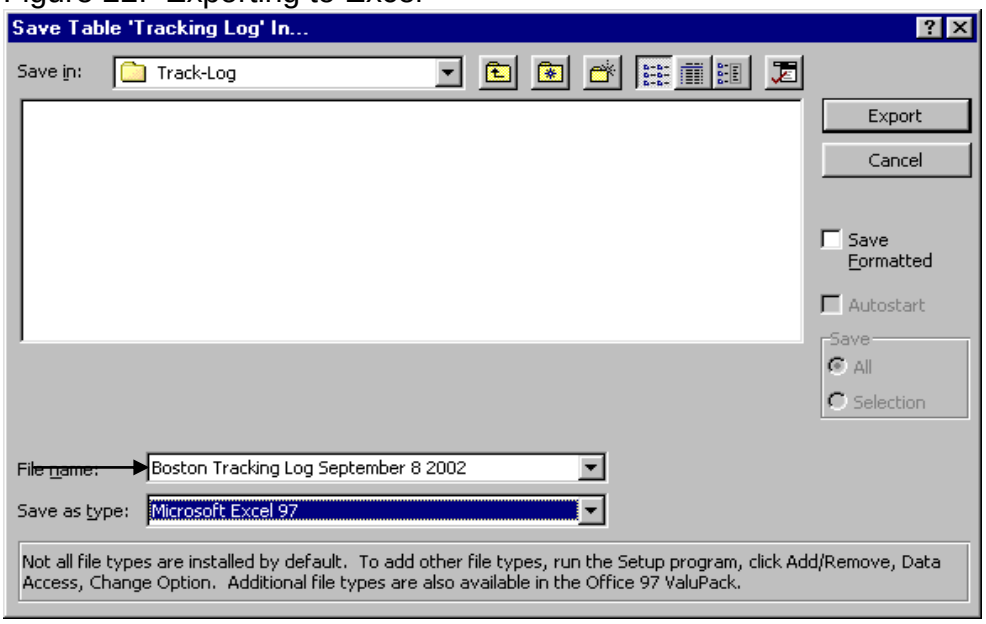
Step 4. You should get a new menu, and the heading should be SAVE TABLE 'TRACKING LOG' IN. There are three things that must be completed in this section (see Figure 21).

1. Go to the FILE NAME menu at the bottom and change the FILE NAME to ***(site)*** **Tracking Log** ***(date)***. For instance, ***Boston*** **Tracking Log** ***Sept 8 2002*** would indicate that it is the tracking log from the Boston site, sent on September 8, 2002. *Please note that there is no punctuation in the file name, but there are spaces.*

2. Below the FILE NAME menu, is a drop down menu labeled SAVE AS TYPE. Please change the file type to MICROSOFT EXCEL **97**.

3. Click the EXPORT button.

Figure 22. Exporting to Excel



Step 4. E-mail the file.
If you have questions about sending a file as an e-mail attachment, please contact the CCC.

MATCHING PSC/DCC ID'S TO TRACKING LOG IDS

The MRI Objective-2 Tracking Log has been constructed in such a way that the PSC and DCC IDs for candidates are **not** saved in the Tracking Log. Therefore, it is necessary to provide the CCC, under separate cover, the DCC ID, PSC ID, Tracking Log ID and Date of time-point (i.e., Date of Behavioral Testing and/or Date of Scan).

Sites are encouraged to keep track of this as each scan is done so that the information is readily available when requested. This can be done conveniently by adding a new table to the Tracking Log Access file or by tracking in a separate Excel file.

Index of Tracking Log Figures

OBJECTIVE – 2

APPENDIX-C QUALITY CONFIRMATION PROCESS

ALL BEHAVIORAL TESTING & QUESTIONNAIRES

To assure that data is being collected and entered into the database in a consistent manner, a number of Quality Confirmation processes have been developed. All examiners and interviewers working on the project must satisfactorily complete an initial and ongoing Quality Confirmation Process. The QC process for each behavioral tester includes videotaping of behavioral testing and sending the videotapes and hard-copies of completed (i.e.,filled-out) test booklets and scoring pages to the CCC for QC evaluation. Written feedback about testing performance will be provided to the tester and the site for each individual test undergoing QC evaluation. Performance for test administration and scoring of each test is rated as:

- Administered and Scored Correctly – Passing (i.e., ≥ 90% agreement for administration and scoring between the tester and the QC evaluator)
- Provisionally Passing (i.e., ≥ 90% agreement for administration and scoring between the tester and the QC evaluator) but potentially significant errors, e.g., borderline passing agreement of 90-92%), or
- Not Administered and/or Not Scored Correctly – Not Passing (≤ 89% agreement between the tester and the QC evaluator).

New Testers

The QC process for behavioral testing has two phases, new testers (no previous QC evaluation) and experienced testers (previously passing QC evaluation). Examiners begin with “practice children” for initial QC evaluation and then move to “real participants” for maintenance of QC standards. New testers should administer the entire battery of neurobehavioral testing to practice children within the age subgroup (i.e., 0:3 to 0:11; 1:0 to 2:11; and 3:0-4:5) that they will be testing until achieving passing ratings from the CCC for all tests within the battery. The CCC will notify the Principal Investigator and their designees in writing when the tester is released for testing of real project participants. QC testing materials must be sent to the CCC for QC evaluation for the first five real participants tested. If all of the behavioral testing for these first five real participants is rated as Passing, the tester is assigned experienced tester status. This status is generally maintained for the duration of the project.

Experienced Testers

Once a tester is promoted to Experienced Tester, they begin the ‘ongoing’ behavioral QC evaluation process. Experienced testers are required to submit all behavioral QC testing materials (i.e., videotapes and hardcopies) to the CCC for every sixth project participant undergoing behavioral testing. This process continues for the entire project unless disrupted by the tester receiving a Not-Passing QC evaluation rating for a behavioral test.

For both new and experienced testers, whenever QC for behavioral testing of a real participant is rated as Not Administered and/or Not Scored Correctly, the tester must return to testing practice children and submitting the QC materials to the CCC for evaluation. This process will continue until Passing status is re-achieved, and then the tester will be allowed to return to testing real participants.

In addition, if there is a four month lapse since the last behavioral testing for a real project participant, the tester has to return to testing practice children until passing QC status is re-achieved and the testing of real project participants can resume.

Neurological examinations

Examiners should be provided with exam descriptions as well as gold standard videotapes of the exams being performed with practice children. The Boston site coordinates the neurological exam QC process through the CCC. Prior to the testing of real project participants, examiners are videotaped while administering neurological examinations to practice children, and the tapes and exam booklets are submitted for QC evaluation (passing criterion was >95% agreement with the evaluation). When substitute neurological examiners are needed, they should be trained by one of the original developers of the neurological examinations prior to examining real project participants.

FIGS

The CCC will provide training sessions, including practice interviews. QC evaluation of new FIGS interviewers includes review of audio tapes of interviews that have been conducted with practice parents. The agreement between the trainer and the trainee must be Kappa >.80. Once interviewers achieve passing status real project participants can be interviewed. Once interviewing real participants, all subsequent interviews are audio taped and submitted to the CCC for periodic QC evaluation.

Database Data Entry

In addition to the Database Manual, the DCC and CCC have provided a number of special training sessions for database entry. Three levels of data entry QC are utilized. First, each of the sites should double-check data entry by comparing their hand scoring of tests with the automated scoring in the database. Second, the database is designed such that data entry is completed on screen forms that are modeled after the actual test booklets and scoring pages, and data input is automatically checked by the database for valid types and ranges of scores/ratings and data entry completeness. Hard copies of all behavioral testing and parent questionnaire booklets and scoring forms are sent to the CCC and DCC for every third real project participant tested by a site (selected on a quasi-random basis). The DCC QC evaluation will compare the data on the hard-copies to the data entered into the database. This QC process determines the accuracy of the database data entry for each data entry staff member at each site. The sites correct any errors in their data entry and persistent data input errors require retraining of the site and staff.

QUALITY CONFIRMATION MANUAL--BEHAVIOR
Neurobehavioral Tests, Interviews, & Neurological Exams
Objective-2 (also used for Objective-1)

I. Background

This document has been created based on Quality Confirmation (QC) Subcommittee conference calls and follow-up e-mail discussions. Subsequent revisions have occurred related to group PSC (Pediatric Study Center) conference calls and discussions between the Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC).

Initial QC subcommittee participants: Kelly Botteron (moderator), C. Robert Almli, Jack Fletcher, Gabriel Leonard, & Robert Asarnow.

II. Principle Domains Covered Under Quality Confirmation (QC) Plan

A. Administration and scoring of all neurobehavioral tests, screening interviews, parent/self report forms, and neurological examinations.

1. Neurobehavioral Tests: BSID-II; DAS; PLS-3; CANTAB; WASI; Digit Span and Coding (WISC-III & WAIS-R); WJ-III; CVLT; NEPSY-Verbal Fluency; Handedness; Purdue Pegboard.
2. Screening Interviews: DISC; DPS; FIGS; Telephone Screening Interviews.
3. Parent/Self Report Forms: CAREY; PSI; CBCL; BRIEF; JTCI.
4. Neurological Examinations.

B. Standardization of procedural implementation across PSC sites

1. A significant component of QC is the establishment of clear, standardized instructions for test administration and scoring, which can be followed in a consistent fashion across PSC sites and testers. This specification and standardization will occur in a large part through instructions provided in the Procedure Manuals, the Testing Tips and Clarifications documents, and the feedback associated with the QC evaluation process.
2. Investigators on the QC subcommittee will periodically review and update the instructions in the Procedure Manuals and/or Testing Tips and Clarifications documents. (Last update: Spring-Summer, 2004).

C. Initial QC of new raters/testers (see IV. A.)

D. Ongoing QC monitoring of raters/testers (see IV. B.)

E. The QC Plan does NOT include the ‘training’ of interviewers/testers

III. Quality Confirmation: General Procedures

A. The coordination of all Behavioral QC activities will be centralized within the CCC.

1. All QC materials (e.g., videotapes/audiotapes, paper copies of completed test booklets/score sheets, questionnaire forms, etc.) from the PSC's will be sent to the CCC in a timely fashion (i.e., as soon as possible after completion of testing and scoring), **but no later than two weeks after testing**. **Please do not hold sets of QC materials to mail in groups, as this will delay the QC review process.**

2. The QC materials submitted to the CCC will be logged, tracked, and monitored under the supervision of Botteron and Almli.

3. If QC review will be accomplished at a site other than St. Louis (e.g., Houston), the CCC will forward the appropriate QC materials to the other site for review.

4. Each test (or subtest, as appropriate) sent to the CCC for QC will be rated as:

a. Passing--defined as ≥ 90% agreement with the standard for item administration and scoring (required for valid data when testing real 'scanned' subjects);

b. Provisionally Passing--Minor Problems, potentially passing (may or may not yield valid data); or

c. Administered/Scored Incorrectly--Major Problems, < 90% agreement with the standard for item administration and scoring (invalid data when testing real 'scanned' subjects).

5. Written feedback about administration and scoring performance is provided to each rater/tester by the QC evaluator. This feedback will be provided in the form of checklist review sheets and specific comments. The written feedback will also be forwarded to site's PI (as well as others that the PI may designate), and the DCC.

6. Copies of the QC Evaluation checklists and comments will be retained at the CCC.

7. The CCC will enter all QC related data into a QC database to consolidate results for monitoring the overall QC process and procedures.

8. The CCC will also enter individual QC evaluation results into the Examiner Certification QC fields of the Examiner Certification mechanism of the DCC database. The QC fields of the Examiner Certification mechanism will be used to 'flag' the QC performance of individual testers/raters and their associated testing data.

9. Technically incomplete, insufficient or poor video/audio recordings (e.g., image or sound not adequate for accurate evaluation, missing tests or parts of tests) of testing cannot be accurately reviewed. Such situations are rated as "No QC Decision," and the tester/rater will have to redo the testing and recording with additional practice children for submission to the CCC for QC evaluation.

10. If "correctable" errors (e.g., certain scoring errors) are noted during the QC evaluation process, the rater/tester will be required to correct the error(s) on the score sheets/booklets and in the DCC database. The tester/rater will notify the QC evaluator by sending the corrected score sheets/booklets back to the QC evaluator (via FAX or some form of express mail), who will confirm that the correction(s) has been made in the DCC database. If a subject's profile was already sent to the DCC, the tester/rater will need to contact the DCC to request access to the subject's data so that corrections can be made. **Failure to send corrected materials to the QC evaluator and to make required corrections in the DCC database will result in the test (or subtest, as appropriate) being rated "Administered/Scored Incorrectly." The time allotted to complete this process is one-week following notification unless there are extenuating circumstances that are approved by the CCC.**

IV. Quality Confirmation – Neurobehavioral Testing

A. Initial QC Process for "New" Neurobehavioral Testers/Raters: The steps below will be followed and completed by each new tester/rater using practice children prior to administering any neurobehavioral testing to real subjects:

1. Practice children (in contrast to 'real subjects') are not officially enrolled in this study and are used for QC purposes, e.g., used to demonstrate a tester's readiness to test real subjects. Real subjects are subjects officially recruited and enrolled to be in the study and receive brain scans.

2. Testers/raters must administer the complete, age-appropriate, testing battery to each practice child submitted for QC evaluation. Submission of a partial testing battery (e.g., just the NEPSY and CANTAB) is not acceptable unless requested by the QC evaluator.

3. Age groups: For QC, a tester/rater must administer and submit a complete testing battery with a practice child for each age group that they will be testing for the study. The tester/rater must continue to submit full testing batteries on practice children for a specific age group until the CCC deems the rater/tester ready to test real subjects within that specified age group.

Objective II
a) age 0:0--0:11
b) age 0:12--2:11
c) age 3:0--4:5

Objective I (Visit-1)
a) age 4:6--5:11
b) age 6:0--7:11
c) age 11:0--13:11
d) age >18:0 yrs

Objective I (Visit-2 & 3)
a) age 4:6--5:11
b) age 6:0--16:11
c) age >18:0 yrs

4. If a test on a practice child is QC evaluated as "Administered/Scored Incorrectly," the rater/tester will test another practice child with the full battery of testing appropriate for that aged child and submit those QC materials for evaluation. This process must be repeated until the rater/tester is judged to be administering and scoring the test(s) in an appropriate, standardized fashion.

5. When a tester is deemed prepared to test real subjects by the CCC, the rater/tester, BI, and PI at the PSC site will be notified by the CCC that the rater/tester can administer the tests appropriate to the specified age group(s) of real subjects. Once deemed ready to test real subjects, the rater/tester will provide the CCC with QC materials for the first five real subjects tested to complete the initial QC process for new testers/raters and advance to the status of "Experienced" Tester/Rater.

B. Ongoing QC Process for "Experienced" Testers/Raters: The steps below outline the QC process to be followed by experienced testers/raters for administering any testing to real subjects after completing QC on the first five real subjects.

1. All experienced raters/testers will participate in the ongoing QC process for the duration of the study**.**

2. PSC Sites will submit QC materials to the CCC for every 6th real subject (after the first five real subjects) for the ongoing QC evaluation of testers/raters.

3. In addition, the CCC may randomly request QC materials for the next real subject being tested at a PSC Site; the next real subject being tested by a specific tester/rater, and/or, the CCC may instruct the PSC site to provide QC materials for specific numbers, ages and/or sequences of real subjects (e.g., the next three real subjects). Further, the CCC may request that a tester/rater provide QC materials for testing of practice children.

4. If a tester does not administer a particular battery of testing during a 4-month interval, the tester/rater must stop testing real subjects and submit QC materials for a complete testing battery for a practice child (for the required age groups). As necessary, the tester/rater will need to continue to submit QC materials on practice subjects for review until the CCC deems that the tester/rater is ready to resume testing of real subjects. Once ready to start testing real subjects, QC materials must be submitted to the CCC and passed for the first two real subjects tested after the 'break in testing real subjects'.

5. A tester who fails to remain compliant with standardized administration and scoring procedures, as demonstrated by their QC evaluation results, will be required to stop testing real subjects and provide QC materials on practice children until the CCC deems that sufficient evidence is available to confirm that the deficiency(s) has been corrected.

C. Objective I QC for Visit-2 & Visit-3 – Special Considerations

1. Initial QC process for "NEW" tester/raters is identical to guidelines outlined above (see IV.A)

2. QC Process for "EXPERIENCED" testers/raters:

a. Prior to re-starting the testing of real subjects for Visits ≥ 2 for Objective-1, experienced testers/raters will need to submit QC materials for a complete testing battery on a practice child at 6 years of age or above. If that QC evaluation is passed, the CCC will provide notice that the tester/rater can begin testing real subjects. Then, QC materials need to be provided to the CCC for the first two real subjects tested.

b. If the QC evaluation of the testing for the practice child is not passed, additional practice subjects will need to be tested and QC materials provided to the CCC for evaluation. This process will continue until the tester/rater is deemed ready to begin testing of real subjects and when achieved, will require undergoing QC on the first two real subjects tested.

3. Once "new" and "experienced" testers/raters have successfully passed QC for their real subjects (i.e., five for new, two for experienced) for visits ≥ 2, ongoing QC will be conducted for every 6th real subject as described for Visit-1 (see IV. B.)

4. For PSC sites that will be testing real subjects at <6 years of age for Visits ≥ 2, a practice child at <6 years of age must undergo a complete testing battery and the QC materials sent to the CCC for QC evaluation. The tester/rater must continue to submit full testing batteries on practice children <6 years of age until the CCC deems the rater/tester ready to test real subjects within the <6 year age group. If the QC with the practice child does not pass, testing of additional practice children and QC will be required until deemed ready to test real subjects by the CCC.

V. Implementation of QC Process

A. Videotapes are digitized and digital copies of relevant sections will be created on CD and sent by the CCC to the appropriate QC reviewer.

B. QC reviewers will review QC materials in a timely fashion and complete checklist comment sheets. The CCC will aim to complete QC reviews within two weeks of receipt of materials from the site. QC reviewers will send materials and evaluation feedback to the CCC for tracking and data monitoring. Results of the QC evaluation are sent to the rater/tester, BI, and PI at the PSC site.

C. CD's of testing will be stored in a locked secure site at the CCC. CDs will be destroyed after the database is finalized (i.e., after four to five years).

D. QC Process: Other Points

1. Demonstration Videotapes/CDs – Demonstration CDs of administration of all tests for various ages are created and distributed to each PSC site. These CDs will be helpful for training new and experienced raters/testers in standardized test administration, as well as facilitating the QC process.
2. The QC process will be most effective if the testers/raters send all of the QC materials (including hand scoring) to the CCC within a few of days of testing a subject/child, but not later than two weeks of testing. The CCC will quickly process the QC materials, send the materials to QC reviewers for their reviews, and finally, provide feedback to the tester/rater about the quality of their testing administration and scoring. The CCC's goal is to complete the QC process within 14 days or less following receipt of the QC materials from the PSC site. It is important to note that any missing or incomplete materials will delay the QC process.

VI. Quality Confirmation -- Screening Interviews

A. Long Screening Telephone Interview- Objective I

1. New Interviewers/Raters
   a. ALL interviewers must submit COMPLETE copies (tapes and paperwork) of their first 5 Long Screening Interviews with families who have consented to participate in the phone interview.
   b. Audiotapes and copies of interviews will be forwarded to the CCC where they will be reviewed and evaluated.
   c. Interviews will be considered 'Non-Passing' if there is >1 error in probing/coding exclusions in 5 interviews.
   d. Following review of audiotaped interviews, the CCC will provide feedback to the interviewer, Coordinator, BI, and PI.
   e. If the interviews were judged as 'Non-Passing' then the interviewer must provide audiotapes for review of the next 5 interviews.
   f. If errors are identified in interviews, raters may be requested to re-contact families/subjects to complete or clarify specific questions.
2. Ongoing QC Monitoring: 5 additional interviews would be reviewed/edited per interviewer at approximately 4 & 8 month intervals.
3. QC for visits in Year-2 and Year-4 will be identical to that outlined above.

B. DISC & DPS Interview- Objective-1

1. New Interviewers/Raters

a. All interviewers must submit 2-3 practice subject/parent interviews.

b. All sites must submit their first 5 “real” DISC (parent) interviews and first 5 ‘real’ DPS interviews.

c. Tapes will be reviewed/recoded.

d. Interviewers must achieve greater than 97% agreement across all diagnoses on 5 interviews to be considered “Passing.”

e. If less than 97% agreement, interviewer must submit 5 more interviews for review.

f. If errors are identified in interviews, raters may be requested to re-contact families/subjects to complete or clarify specific questions.

2. Ongoing study phase - Every 6th DISC and DPS interview per interviewer taped, reviewed and passed.

3. QC for Visits in Year-2 and Year-4 – Special Considerations

a. For certified interviewers, the first two DISC-P, DPS, and DISC-Y interviews will be recorded and sent to the CCC. Then every 5th interview will be recorded and sent to the CCC.

b. For new interviewers, two practice interviews need to be taped, reviewed and passed. Then the first five DISC-P, DPS, and DISC- interviews will be taped and submitted to the CCC.

C. FIGS Interview [Objective I and Objective II]

1. New Interviewers

a. New interviewer will complete FIGS training packet and exercises. These will be returned to the CCC for review.

b. New interviewers will then complete 5 FIGS and turn in their completed tapes and paperwork.

i. Kappa should be > 0.8 average across all diagnoses on 5 interviews.

ii. Interview procedures should be appropriately followed.

c. If an interviewer fails to “pass,” as described above, they submit their next 5 interviews for review.

d. If interviews meet b) as above, then the interviewer can proceed with study phase.

2. Ongoing study phase

a. Every FIGS interview will be taped and reviewed/edited.

b. Editing review feedback will be provided by the CCC.

c. Audiotapes will be returned to the sites after approximately one year to erase and reuse.

d. If errors are identified in interviews, raters may be requested to re-contact families/subjects to complete or clarify specific questions.

VIII. Quality Control -- Neurology Exam

A. For initial training and standardization across sites the neurological examiner from each PSC will meet in a central location for a 1-day meeting. Meeting occurred July 11, 2001.

1. At this meeting the neurologists present assisted in the finalization of the standardized neurological exam. Their suggestions were discussed and reviewed in this group format in order to specify the items to increase reliability of administration across sites.

a. Following this meeting, standardized neurological exam forms were finalized.

b. Videotapes of the standardized neurological exam for different age groups were created and distributed to the neurological examiners at each PSC.

B. Each PSC will videotape their first exam of each type to be reviewed by a project PI who will provide feedback to assure standardization across sites.

1. Performance on the exam is passing when >95% of all exam items are administered appropriately.

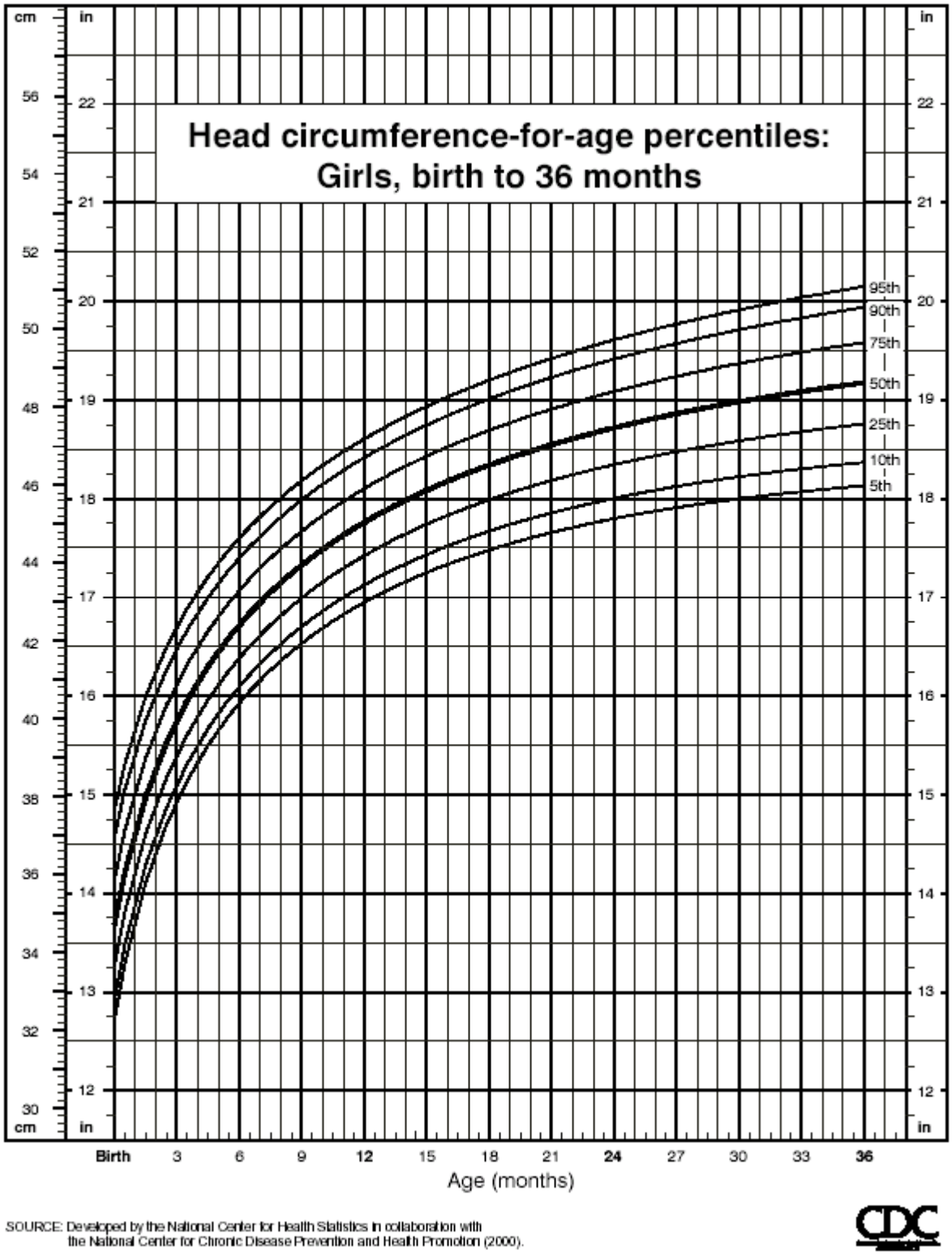
2. If the administration of the neurological exam is judged to be insufficient on > 5% of items administered, then the neurology examiner would be required to test additional practice children. Feedback on deficiencies is provided to the examiner and PI at the site.

3. Examiners with deficiencies will be required to resubmit tapings of additional neurological exams with practice children until passing administration and scoring.

C. QC for visits in year-2 and year-4 will be identical to that described above for baseline.

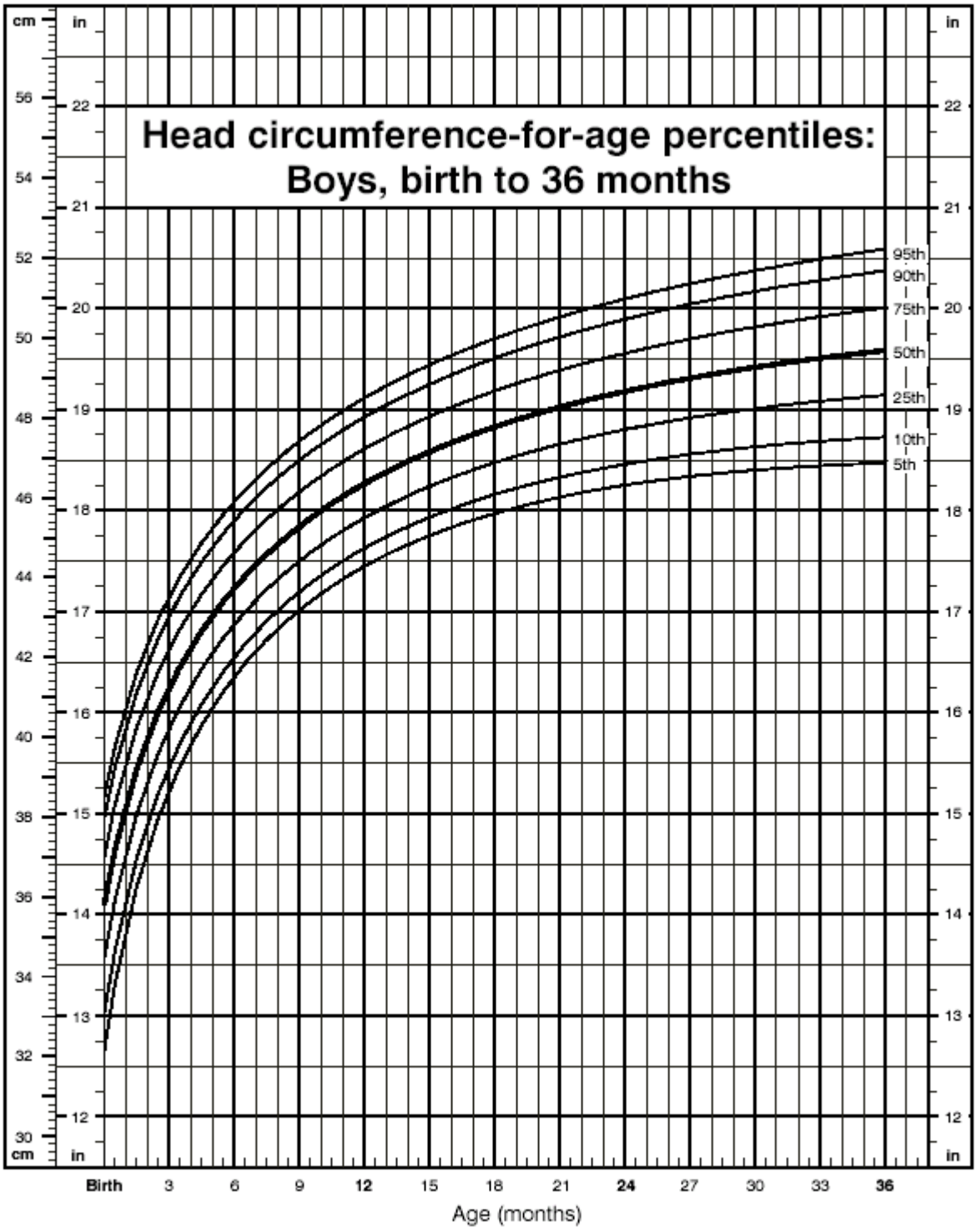
APPENDIX-D GROWTH CHARTS

CDC Growth Charts: United States

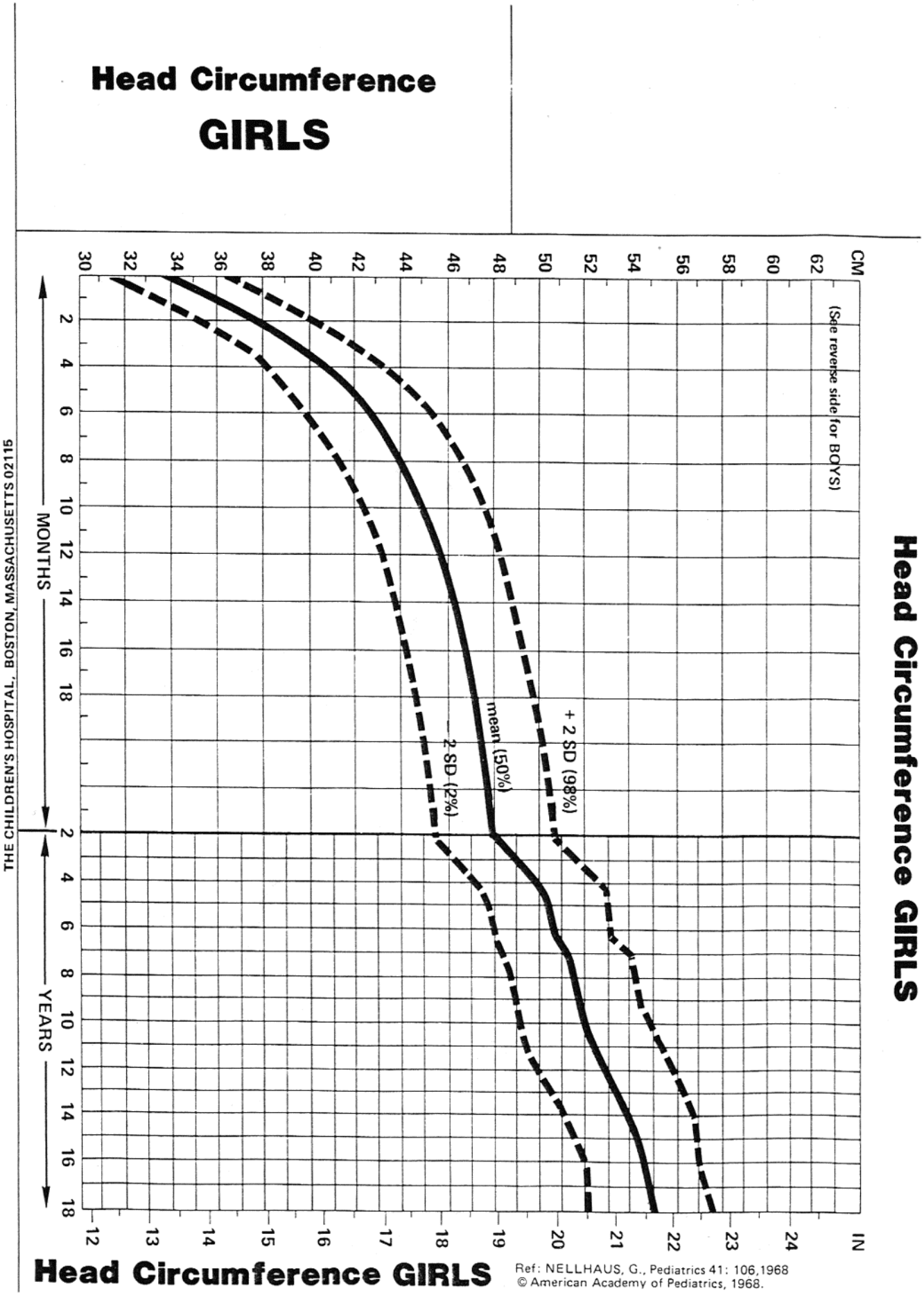


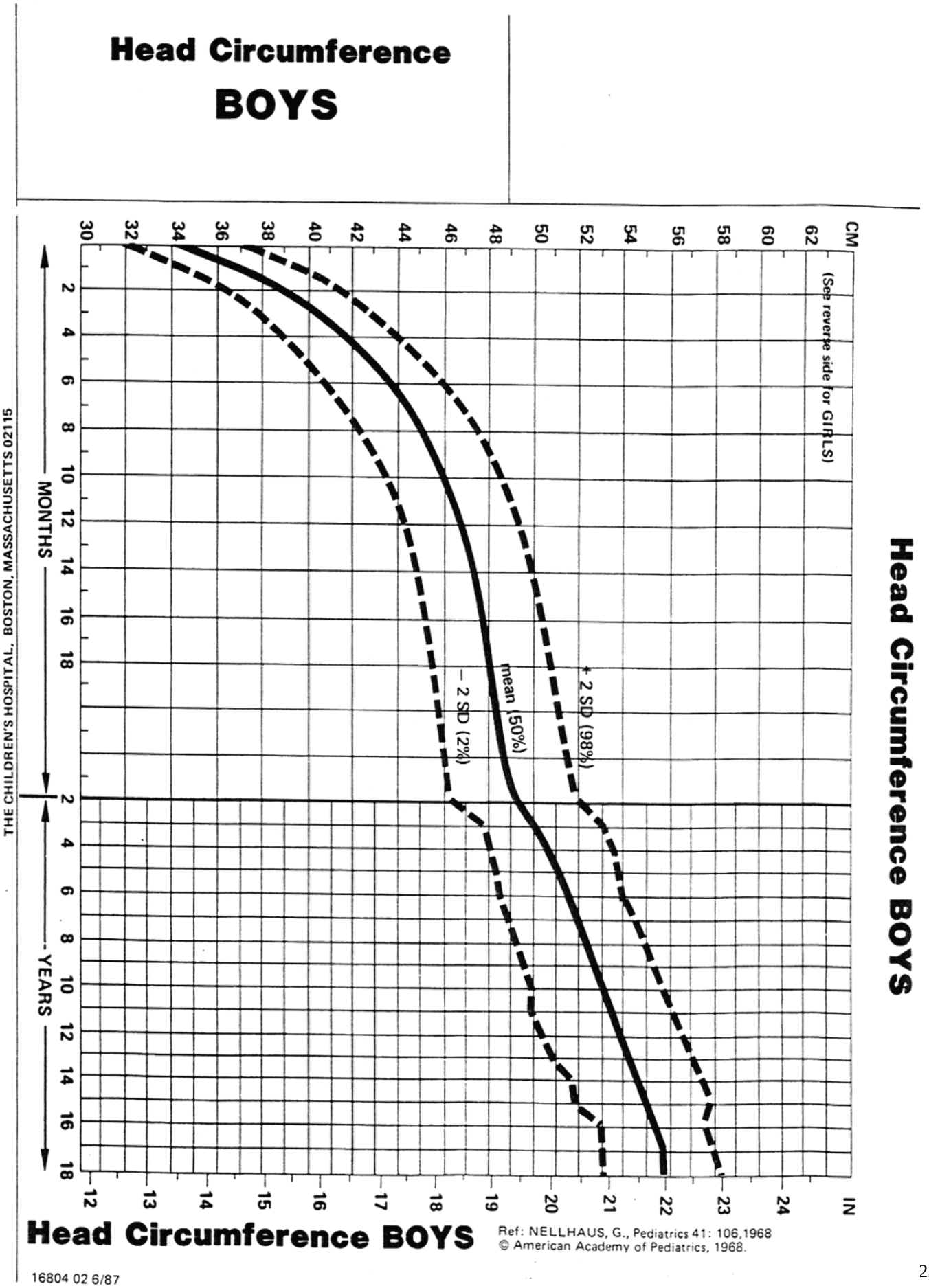
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).

CDC Growth Charts: United States



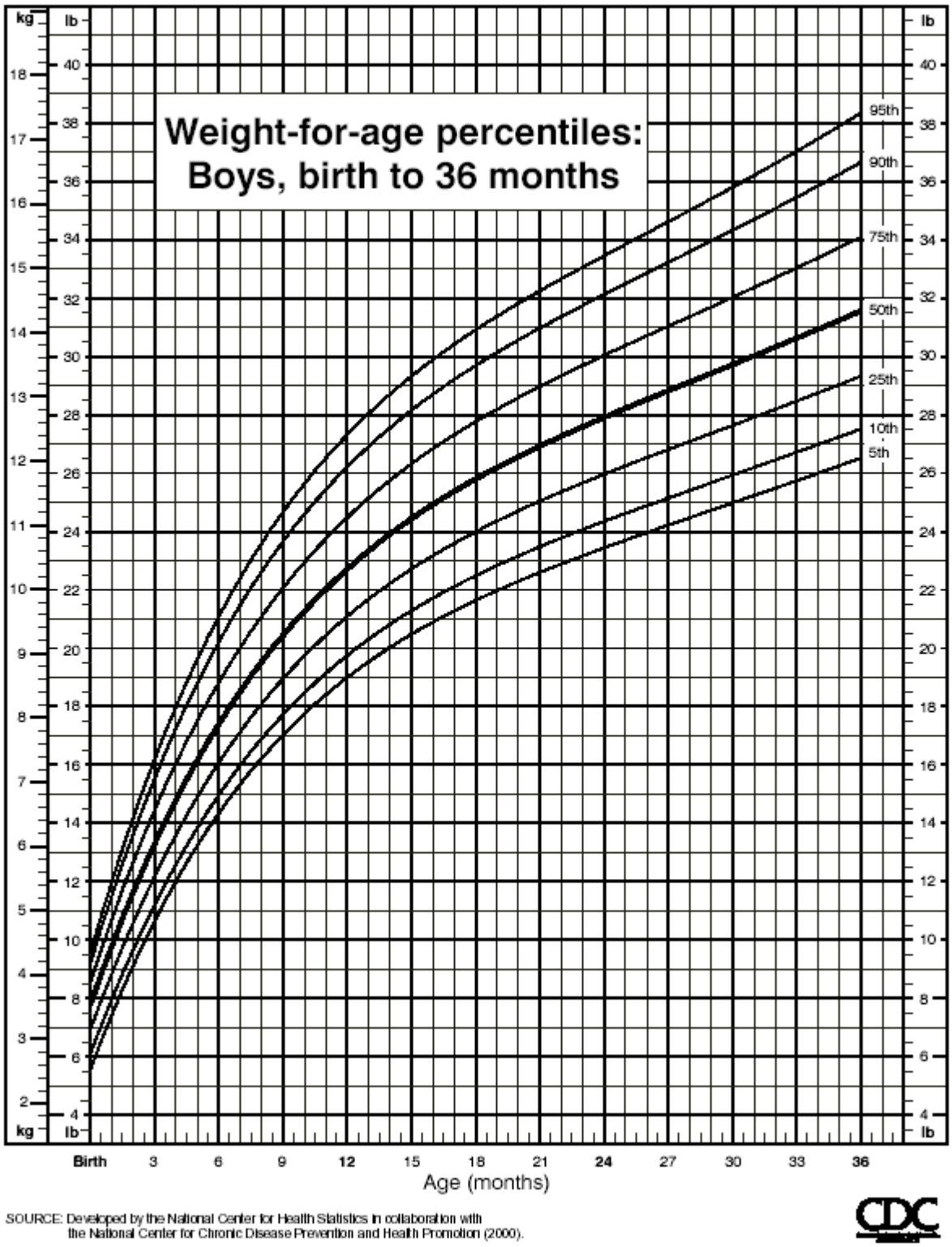
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).


Head Circumference
GIRLS
CM
IN
(See reverse side for BOYS)
+ 2 SD (98%)
mean (50%)
– 2 SD (2%)
MONTHS
YEARS
THE CHILDREN'S HOSPITAL, BOSTON, MASSACHUSETTS 02115
Head Circumference GIRLS
Ref: NELLHAUS, G., Pediatrics 41: 106,1968
© American Academy of Pediatrics, 1968.
Head Circumference GIRLS



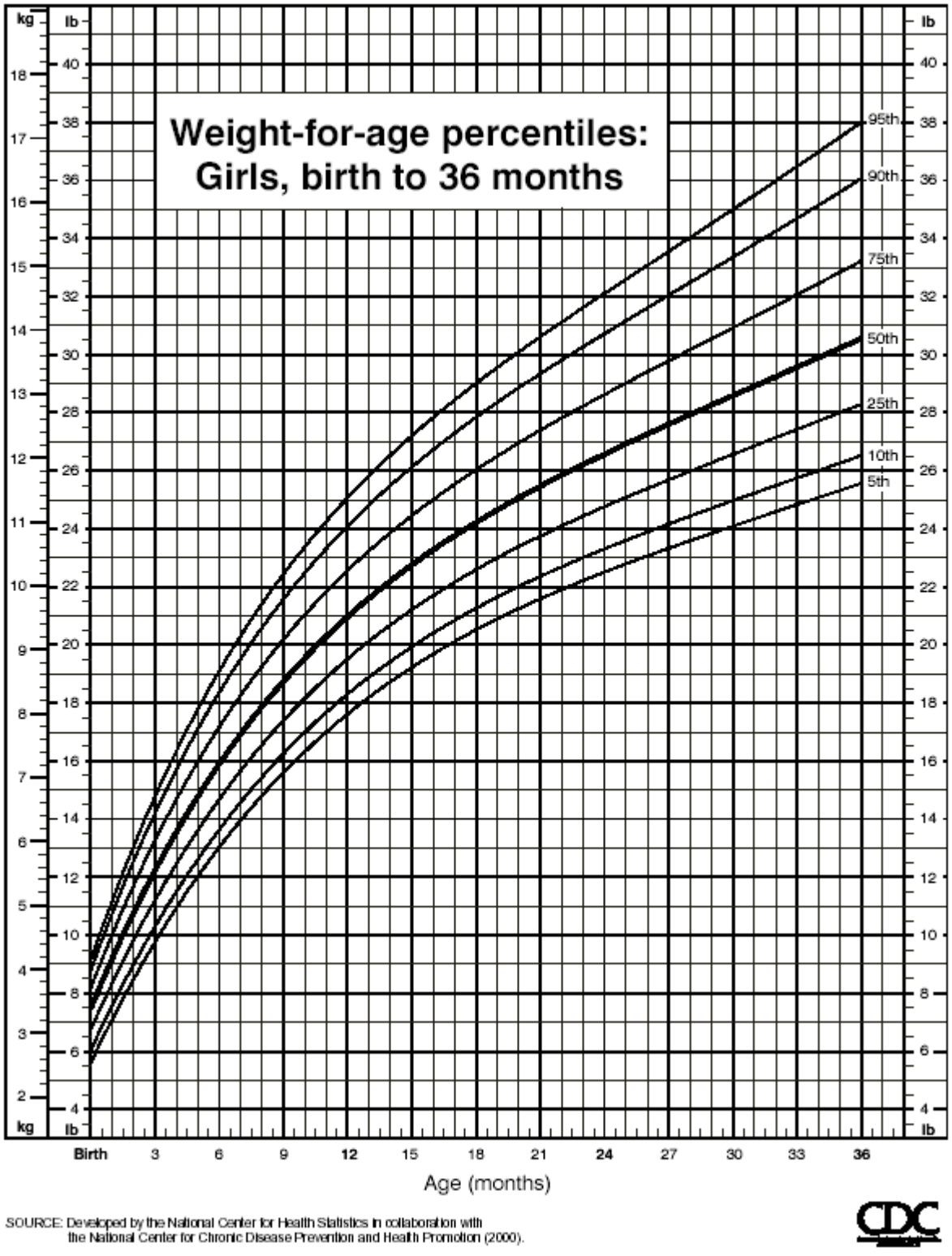
Head Circumference BOYS

CDC Growth Charts: United States



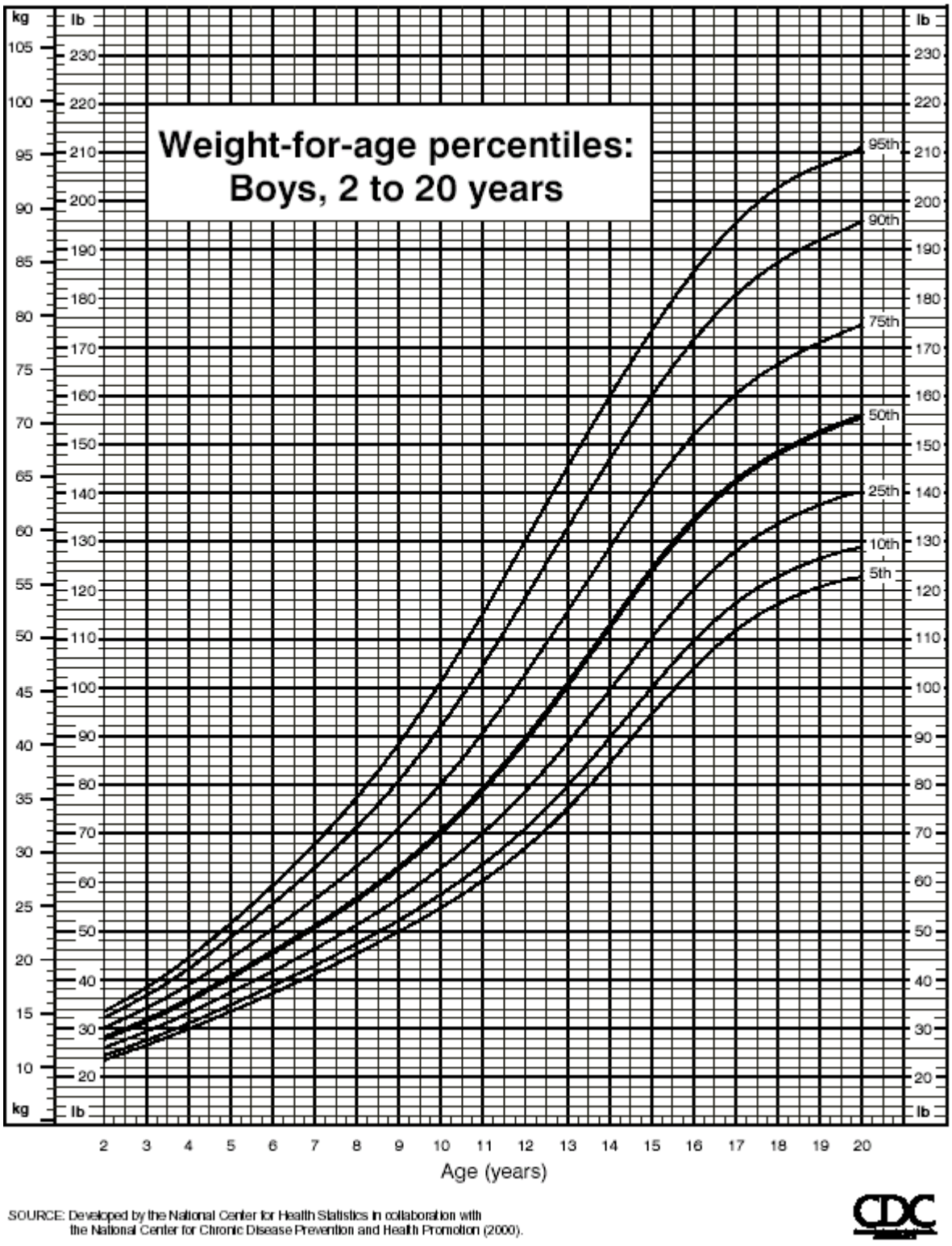
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).

CDC Growth Charts: United States

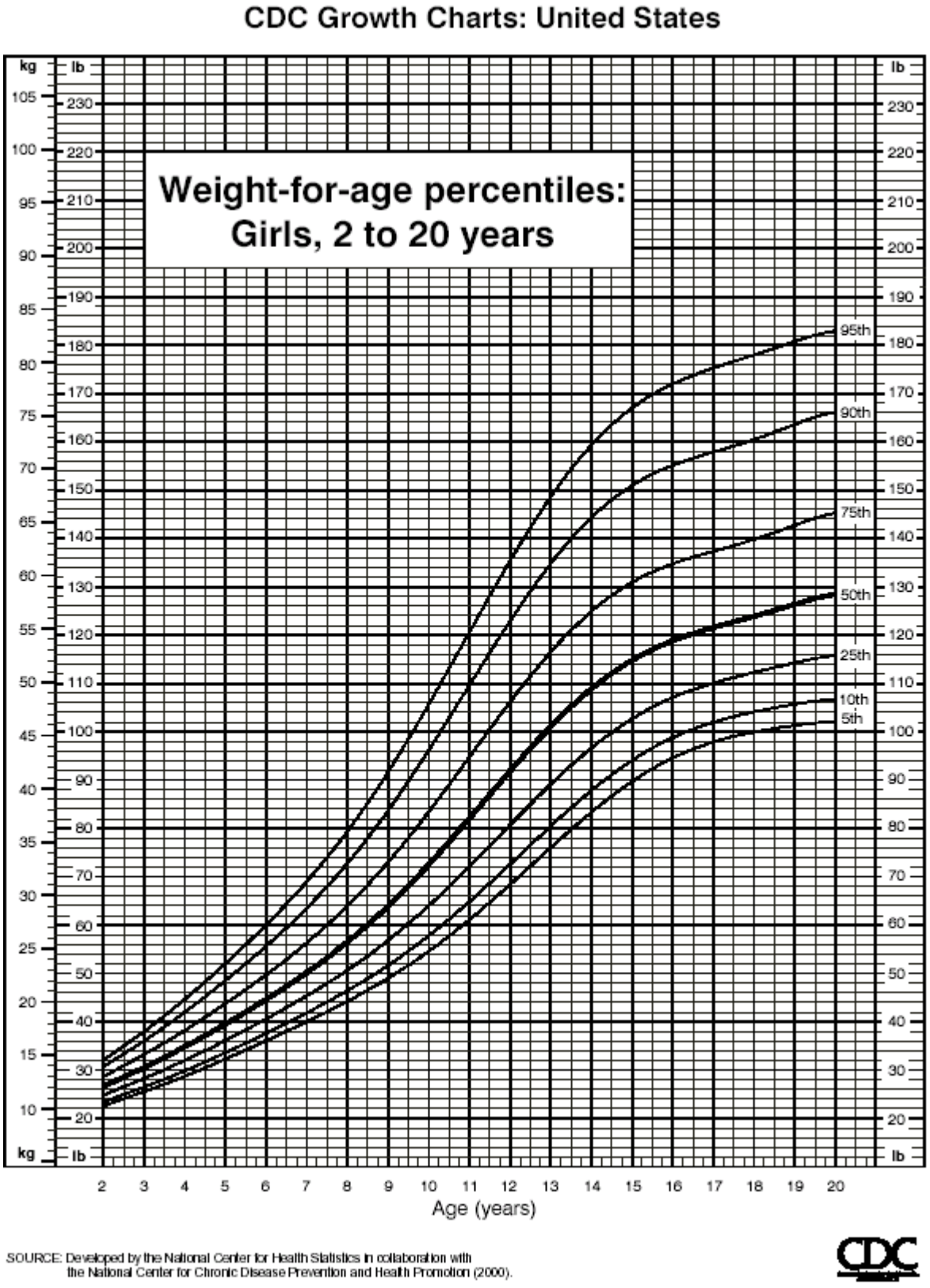


SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).

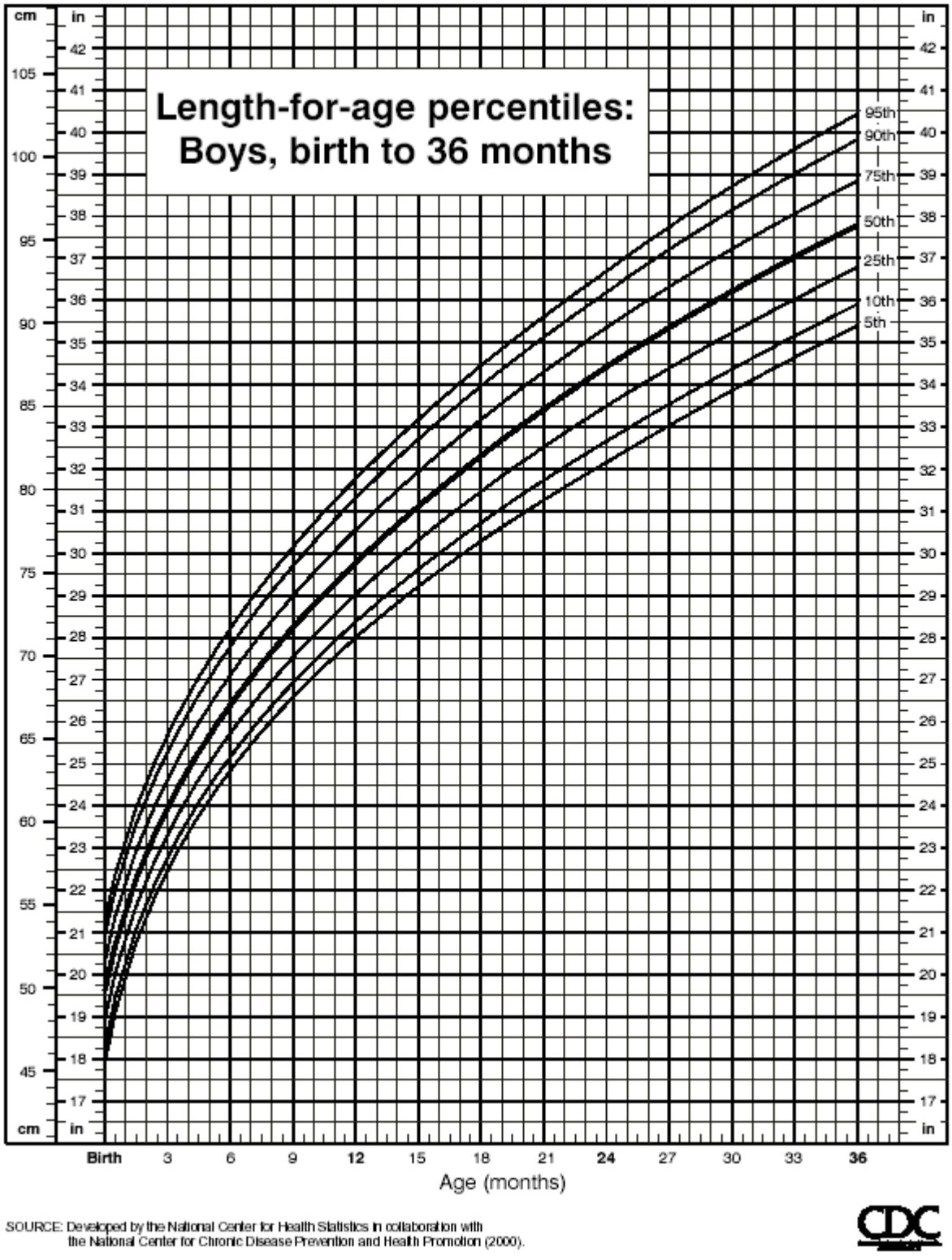
CDC Growth Charts: United States



SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).

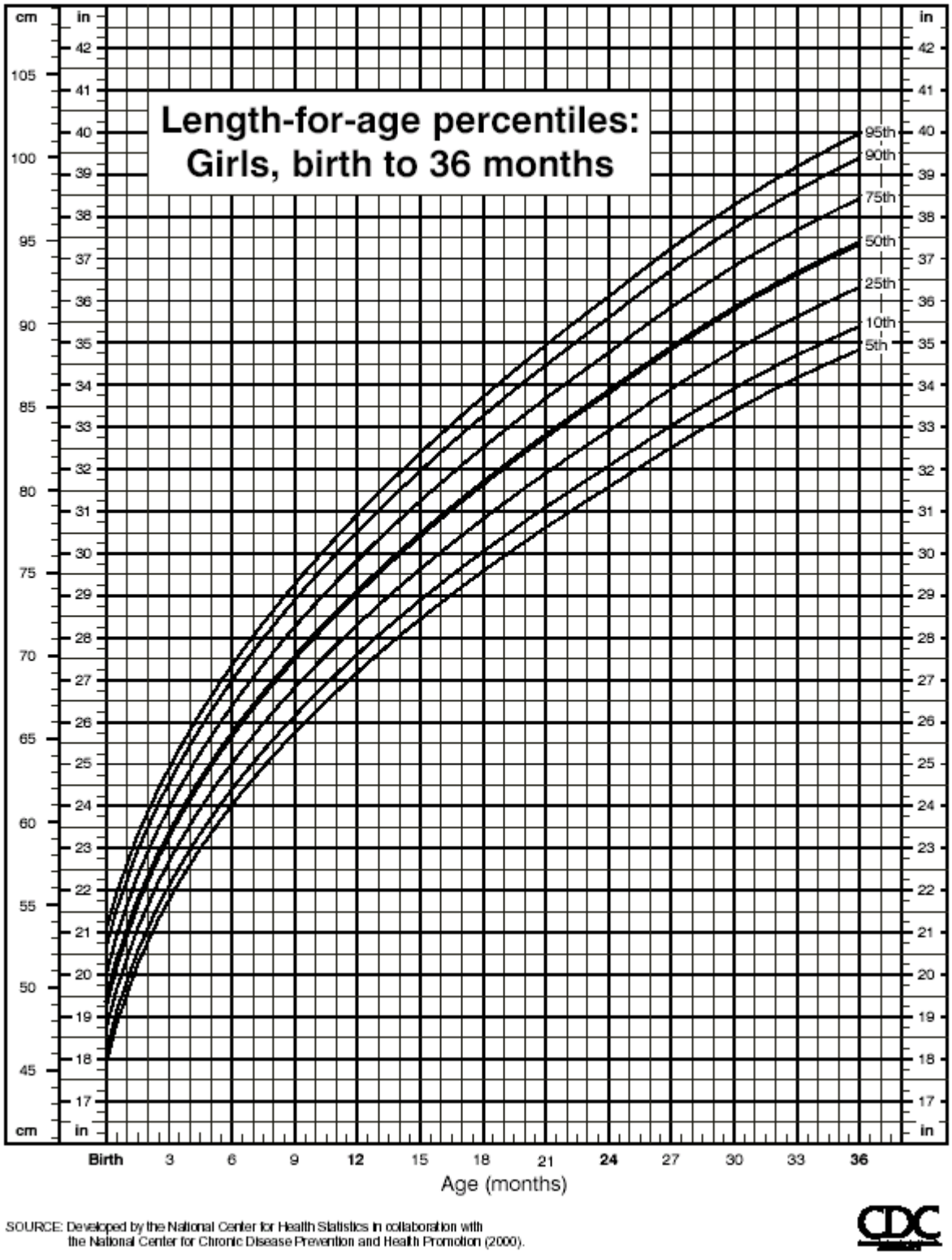

CDC Growth Charts: United States
Weight-for-age percentiles:
Girls, 2 to 20 years
kg
lb
95th
90th
75th
50th
25th
10th
5th
Age (years)
SOURCE: Developed by the National Center for Health Statistics in collaboration with
the National Center for Chronic Disease Prevention and Health Promotion (2000).
CDC

CDC Growth Charts: United States



SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).

CDC Growth Charts: United States



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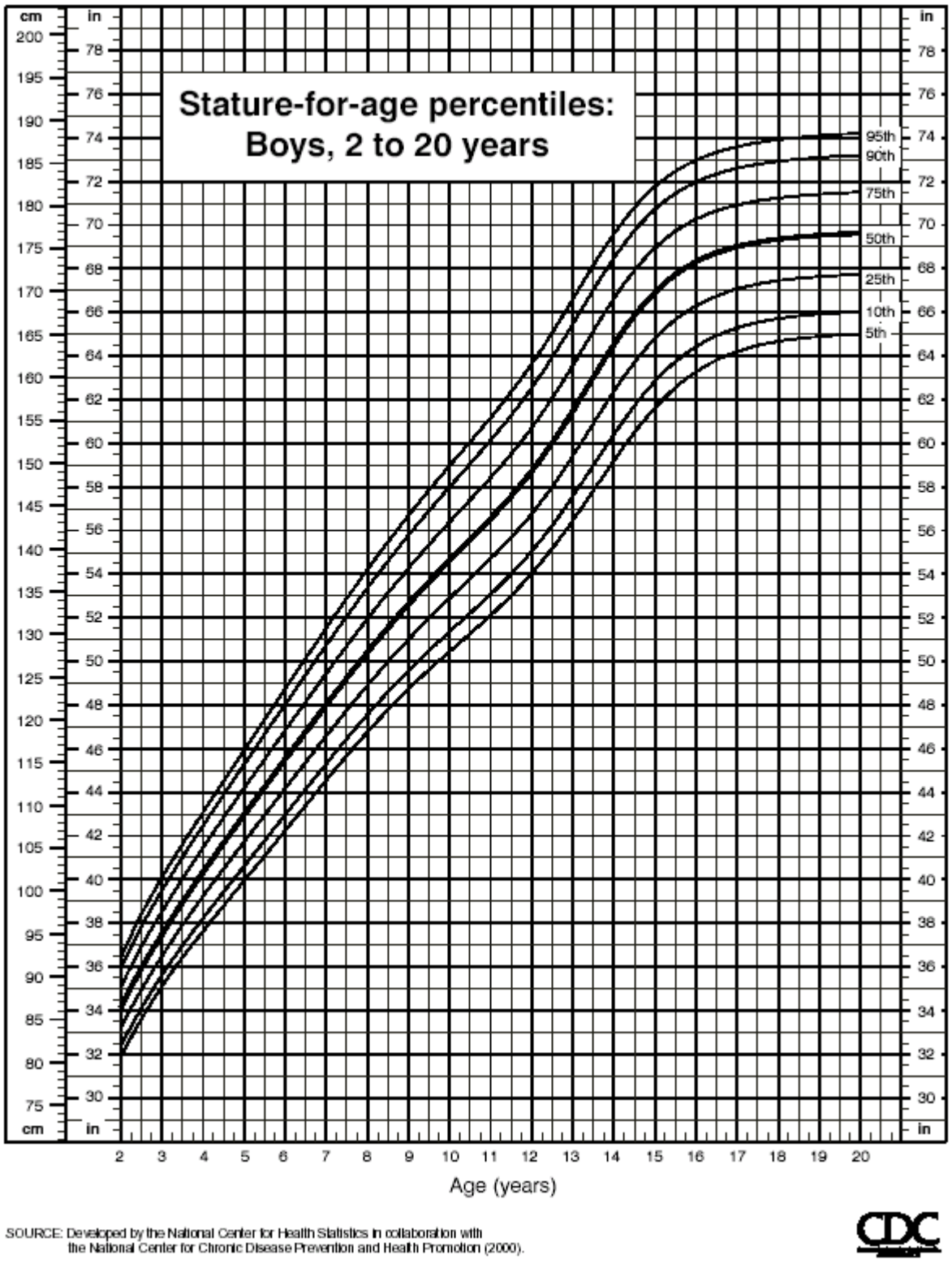
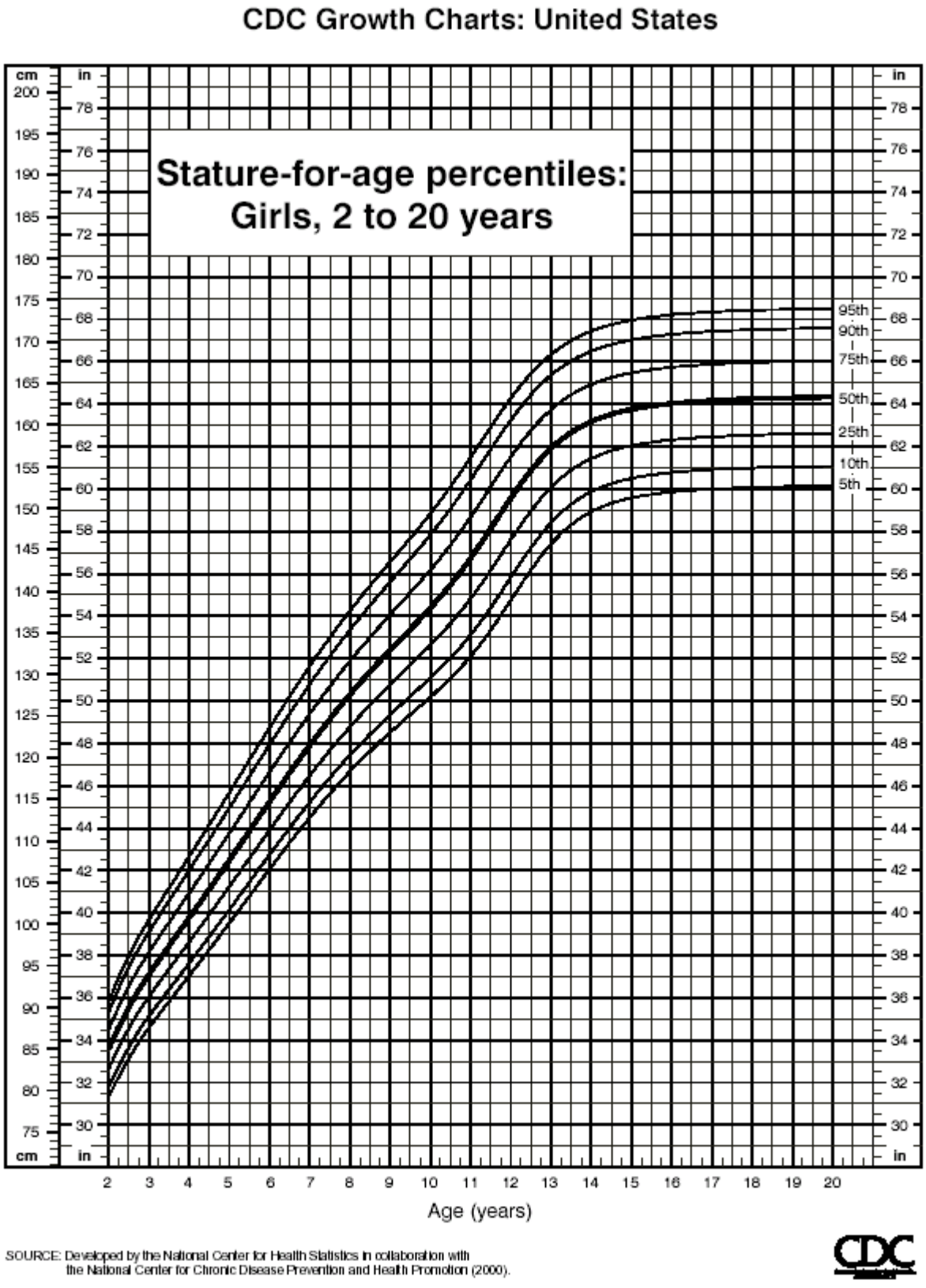
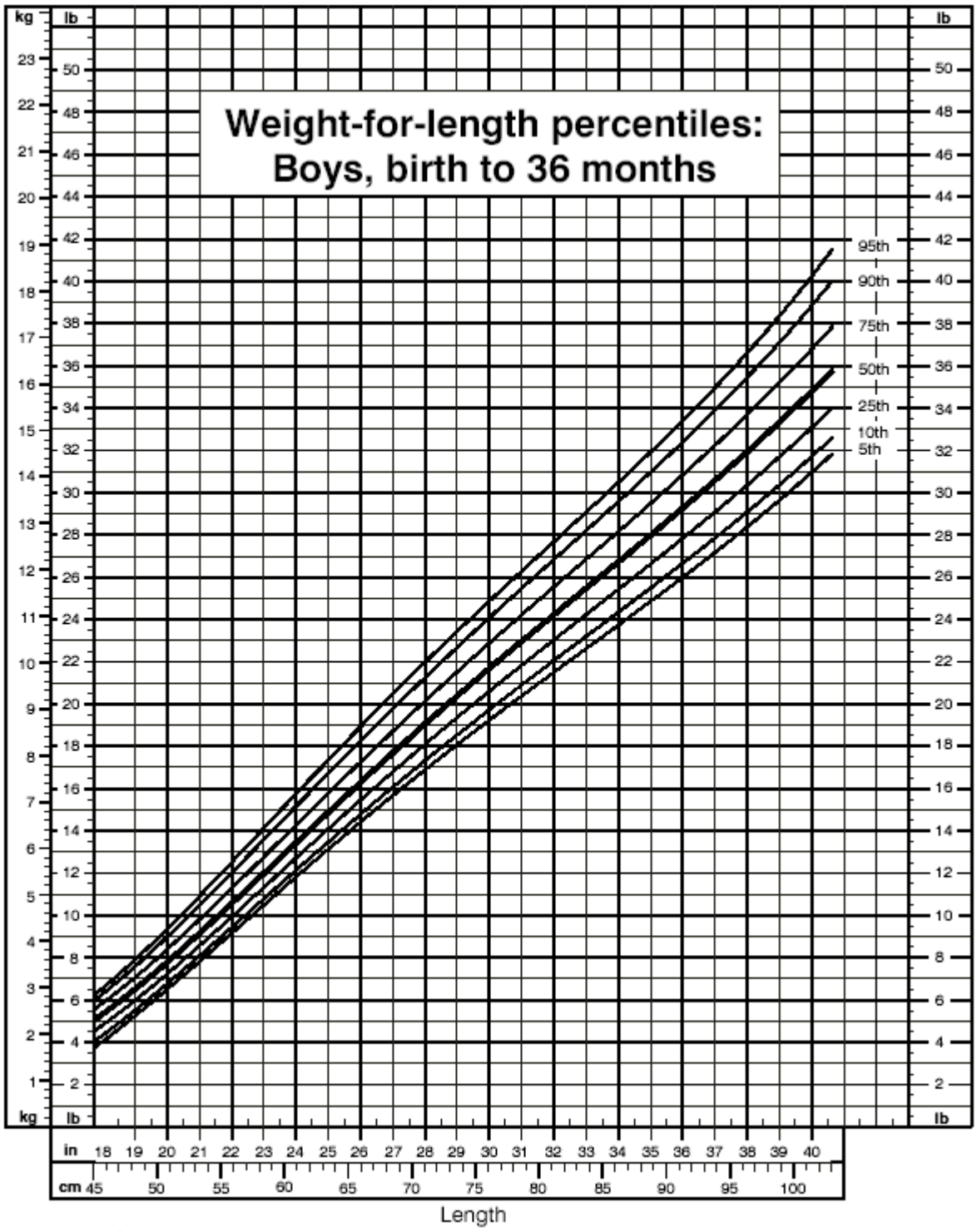
CDC Growth Charts: United States




CDC Growth Charts: United States
Stature-for-age percentiles:
Girls, 2 to 20 years
cm
in
95th
90th
75th
50th
25th
10th
5th
Age (years)
SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
CDC

CDC Growth Charts: United States



Revised and corrected June 8, 2000.

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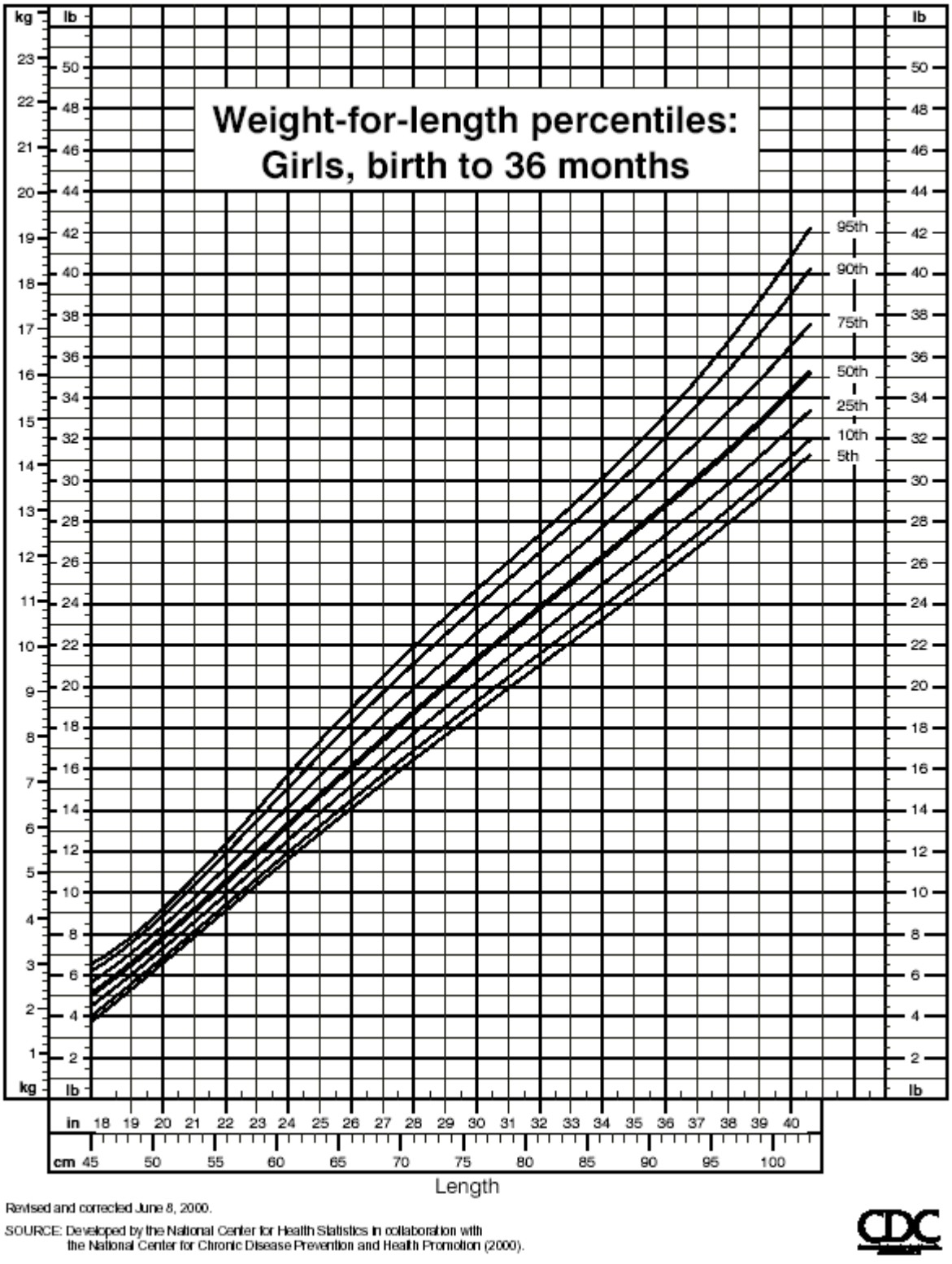
CDC Growth Charts: United States



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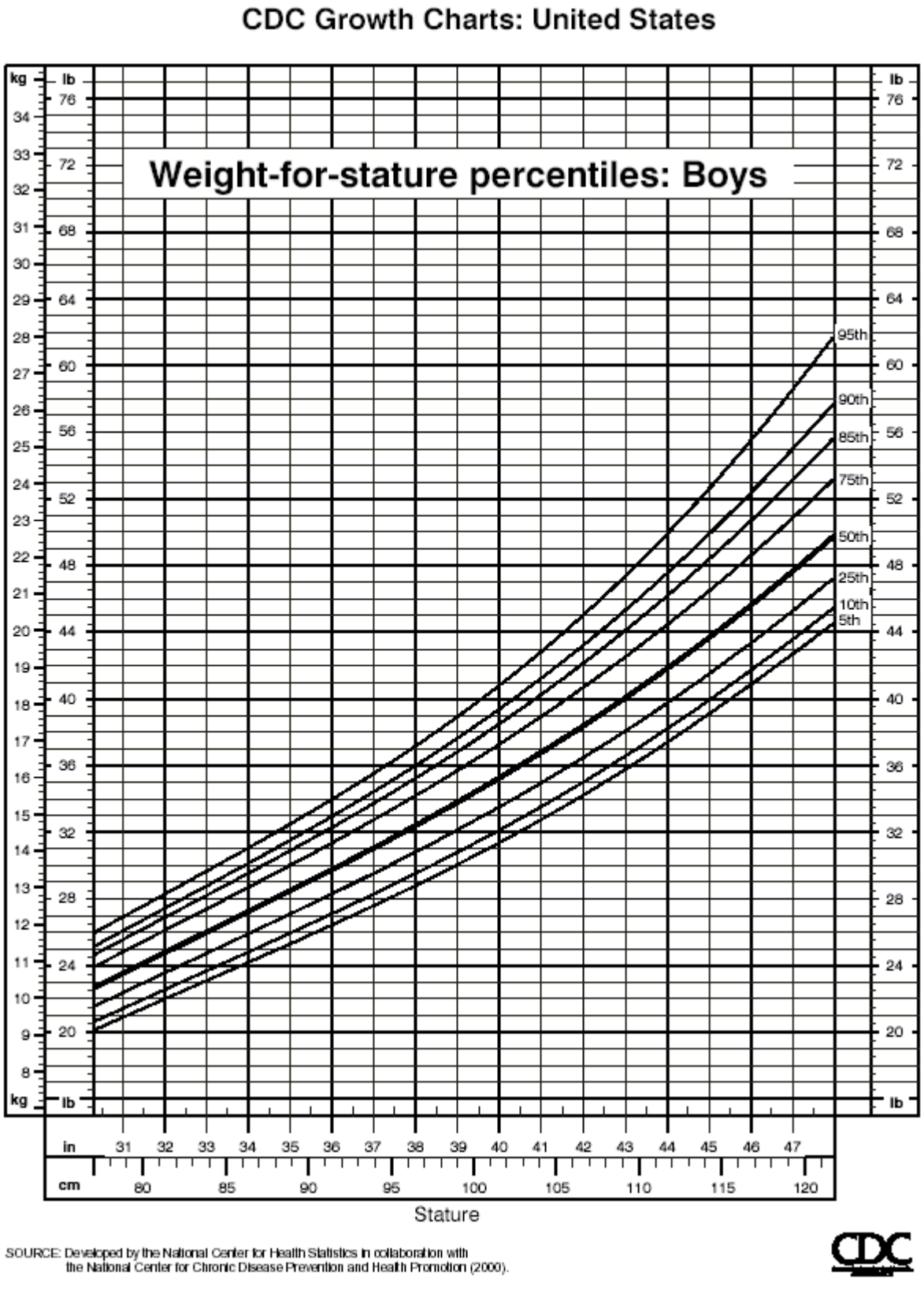
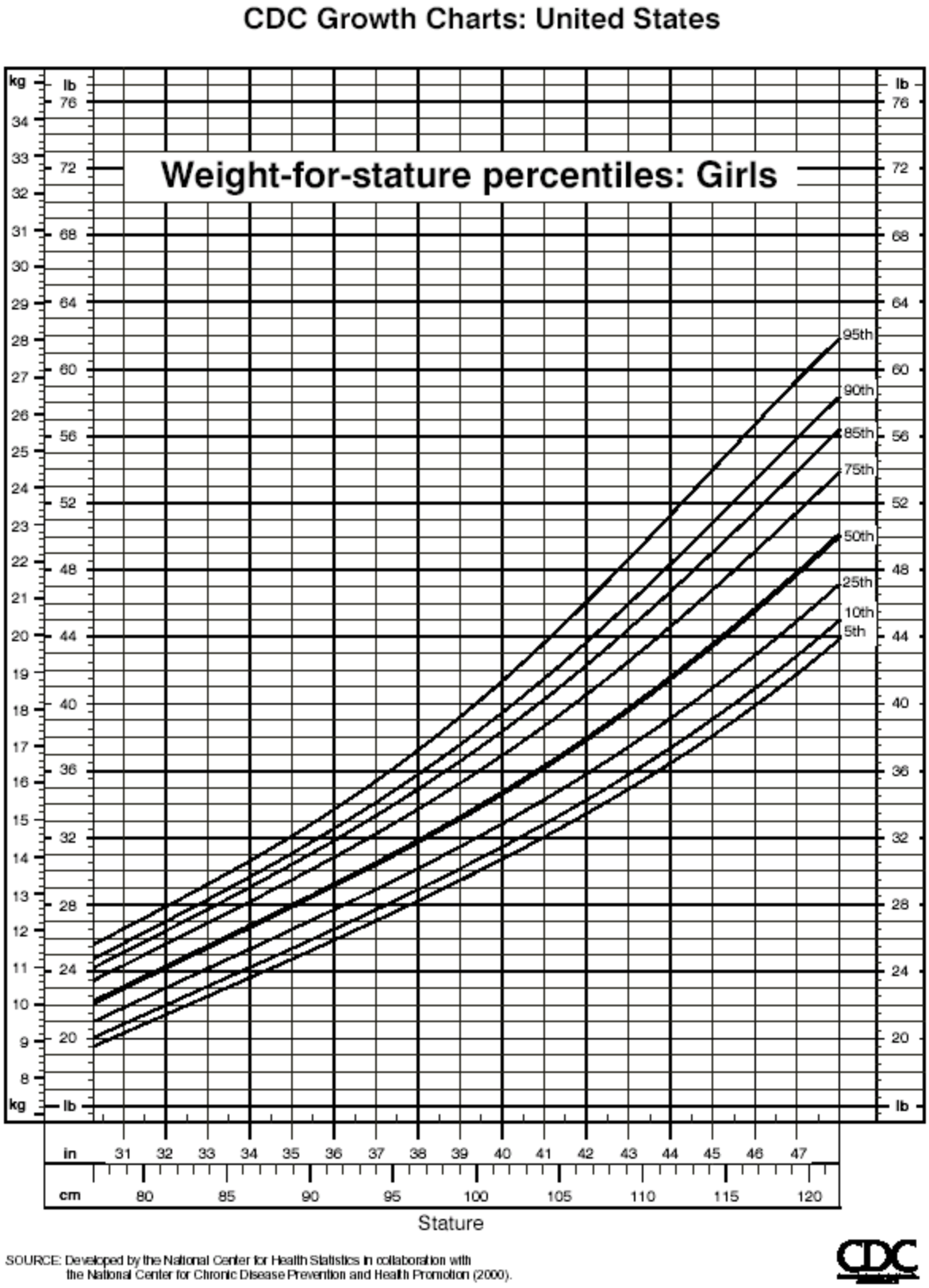


BIRTH TO 5-YEARS



BIRTH TO 5-YEARS